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Quality Management System Manual

Revision M

Certified to AS9100 Revision C

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Approvals

Name	Title	Name	Title

Revision History

Letter	Date	Brief Description
A	10-07-09	Initial Release of document for management review prior to implementation
B	02-01-10	Clarification revisions throughout, enhancement of risk assessment and configuration management sections, addition of section numbers to all headings, rewritten improvement recommendation procedure. Enhancement of document control, nonconforming product and records control procedures. Record retention times increased to meet general aerospace requirements.
C	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 nonconforming material.
F	07-01-11	Updated section 11.8 to require issue log entry of corrective actions, provide option of using QAF-10, update preventive action to improvement recommendation, update Sales Engineering Manager to Director of Sales and Marketing, update Training Matrix to Training Tracking Grid, update section 5.4.3 outlining supplier responsibilities to document completion.
G	09-07-11	Section 4.4.3 revised “access” to “assess”, section 1.1 revised scope to include “Contract Manufacturing”, updated section 1.2 Quality Policy Statement, revised “Improvement Recommendation” to “Preventive Action”, added section 3.7 Project Management, and updated section 6.4.3.3 to include temperature requirements.
H	06-29-12	Revised Section 5.4.3.3 Evaluation Criteria, 8.1 Scope and Purpose added, updated formatting.
I	8-6-12	Revised Section 3.4.1.1 adding paragraph on Objective Measurement Cover Page; added bulleted item under Section 8.3.1 regarding disposal of records; inserted new sub-section 5.4.3 regarding Control of Work Transfers, thereby renumbering subsequent headers in section; revised Section 6.2 record format for Equipment Maintenance; added Section 6.5 Post Delivery Support.
J	2-19-14	Revised Section 5.4.4.5 late definition from being past their quoted delivery date to past their Promised Date in Witco Shop.
K	8-18-14	Revised Section 6.4.3.3 to address creation of a monthly report of equipment due for calibration, and the recall and calibration of that equipment. Revised Section 9.6.2 to include the automatic software creation of an issue if there is an audit finding.
L	9-23-14	Revised Section 10.3.1 adding timely notification of concerned parties if it is suspected that nonconforming product has been shipped.
M	9-17-15	Revised the entire manual to follow the standard format.

4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

This Quality Management System (QMS) Manual has been established and documented by Witco Inc. hereafter referred to as Witco, for the implementation of customer, supplier, statutory and regulatory quality requirements and the requirements of AS9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, corrective and preventative action and management review.

Witco has

a) identified the following processes needed for the QMS and their application throughout the organization,
   - Management
   - Contract Administration
   - Purchasing
   - Manufacturing
   - Storage and Shipping

b) determined the sequence and interaction of these processes and documented them on the Flow Chart in Section 4.2.2,

c) implemented the use of internal audits, work center audits, business objectives and key performance indicators (KPIs) to ensure the operation and control of these processes are effective,

d) ensured resources and information are available to support the operation and monitoring of these processes through Management Review Meetings (MRM),

e) established a system to monitor, measure and analyze these process utilizing KPIs, business objectives and MRMs, and

f) implemented actions that support the planned results and continual improvement of these processes through KPI's and Preventive Action in the Issues Log.

These processes will be managed by Witco in accordance with the requirements of the AS9100 Rev. C International Standard.

When Witco chooses to outsource processes that affect product conformity, including management activities, provision of resources, product realization, measurement, analysis or improvement, it will adhere to Section 7.4 of this QMS Manual.

4.2 Documentation Requirements

4.2.1 General

This Quality Management System contains

a) documented statements of our Quality Policy (Section 5.3), business objectives and KPIs (Section 5.4.1),
b) Witco's QMS Manual,
c) reference to the following procedures and records which are required by AS9100, ISO13485 or ISO9001.
   - Control of Documents (Section 4.2.3)
   - Control of Records (Section 4.2.4)
   - Control of Nonconforming Product (Section 8.3)
   - Internal Audit (Section 8.2.2)
   - Corrective Action (Section 8.5.2)
   - Preventive Action (Section 8.5.3)
d) forms and records determined necessary by Witco to ensure effective planning, operation and control of Witco's processes which can be located by referencing the Master Documents List in Witco Shop.

Witco ensures that employees have access to and are aware of the QMS Manual, processes, work instructions, forms and records (as applicable) through the Master Documents List and any changes (reference QAF-140 New/Revised Document Request). We also provide customer or regulatory authority's access to QMS documentation as needed.

4.2.2 Quality Manual

Witco established and maintains this QMS Manual which includes

a) the scope of Witco's QMS and details of and justification for exclusion.

   "Manufacturing precision machined components and assemblies."

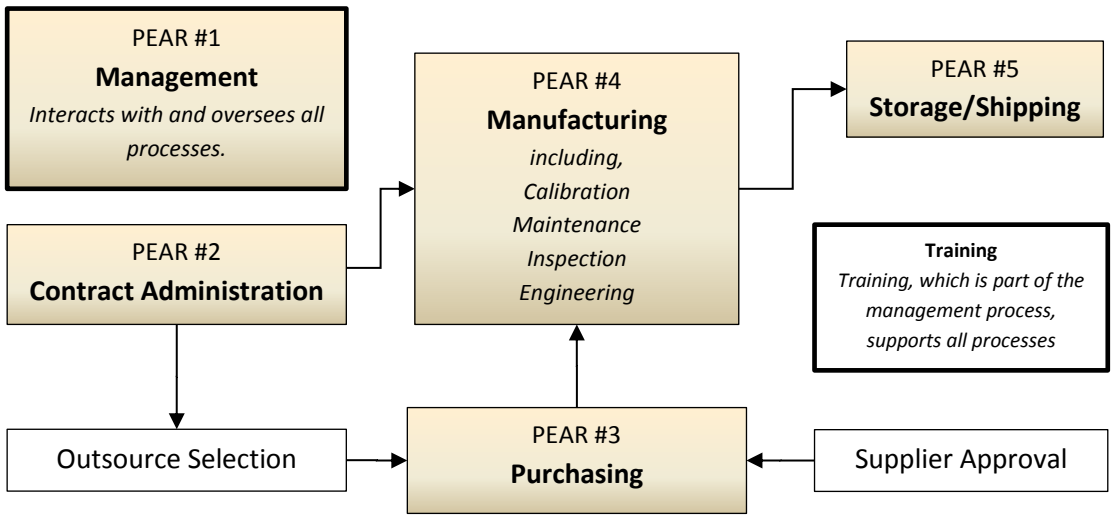
   Exceptions will include situations where partial or no compliance is required and will be specifically designated in the contract or product work instruction.

Exclusions from AS9100, ISO13485 or ISO9001 and Justification for Exclusion:

Clause	Topic	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.

b) documented procedures that are located throughout Witco's QMS Manual.
c) interaction between the processes of the QMS.

Process Sequence and Interaction Flow Chart



PEAR #1 Management

Process Owner: Management Representative

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.

Inputs

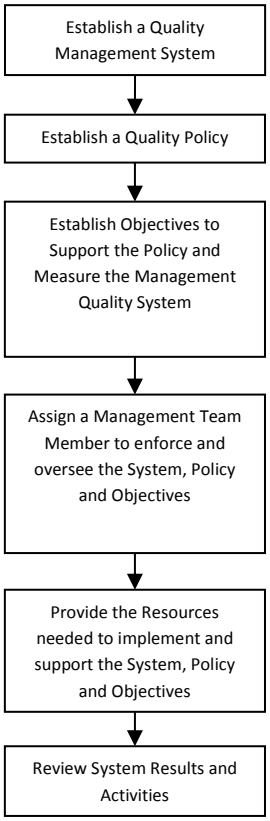
- Results of Audits
- Customer Feedback
- Business Objectives & KPIs
- Previous MRM Action/Minutes
- Changes that could affect the QMS
- Recommendations for Improvement
- Effectiveness of Training
- Issues Log

Outputs

- Internal Communication
- QMS Improvements
- Product Improvements
- Management Review Minutes
- Resource Needs

Standard Sections to be Audited:
4.1, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 5.1, 5.2, 5.3, 5.4.1, 5.4.2, 5.5.1, 5.5.2, 5.5.3, 5.6.1, 5.6.2, 5.6.3, 6.1, 6.2.1, 6.2.2, 6.3, 6.4, 8.1, 8.2.1, 8.2.2, 8.2.3, 8.4, 8.5.1, 8.5.2, 8.5.3

Management Process



PEAR #2 Contract Administration

Process Owner: Director of Marketing and Sales

The contract administration process is responsible for the preparation of customer quotations, review of product requirements and planning of product realization.

Inputs

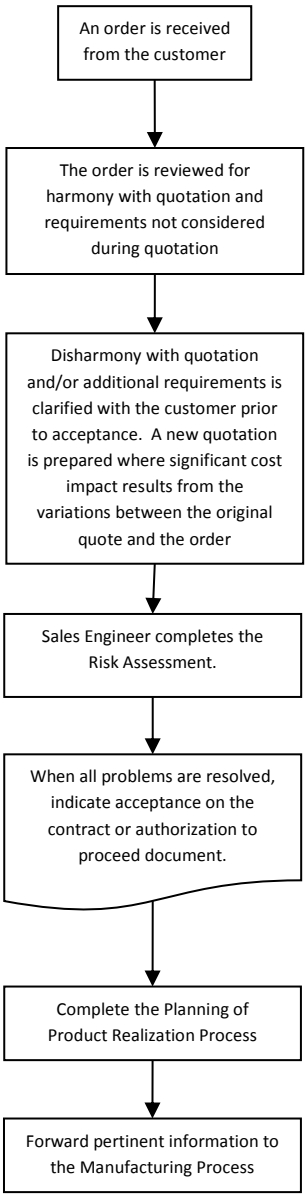
- Customer Purchaser Order
- Customer Print
- Customer Requirements

Outputs

- Sales Order
- PO Acceptance
- Risk Assessment
- Shop Paper
- Shop Print
- Process Drawings
- Inspection Reports
- Suggested Gages
- Tool Sheet
- Resource Needs
- Vendor Quotes

Standard Sections to be Audited:
4.2.3, 4.2.4, 7.1, 7.1.1, 7.1.2, 7.1.3, 7.2.1, 7.2.2, 7.2.3

Contract Administration



PEAR #3 Purchasing

Process Owner: Director of Marketing and Sales

The purchasing process is responsible for the procurement of materials and services.

Inputs

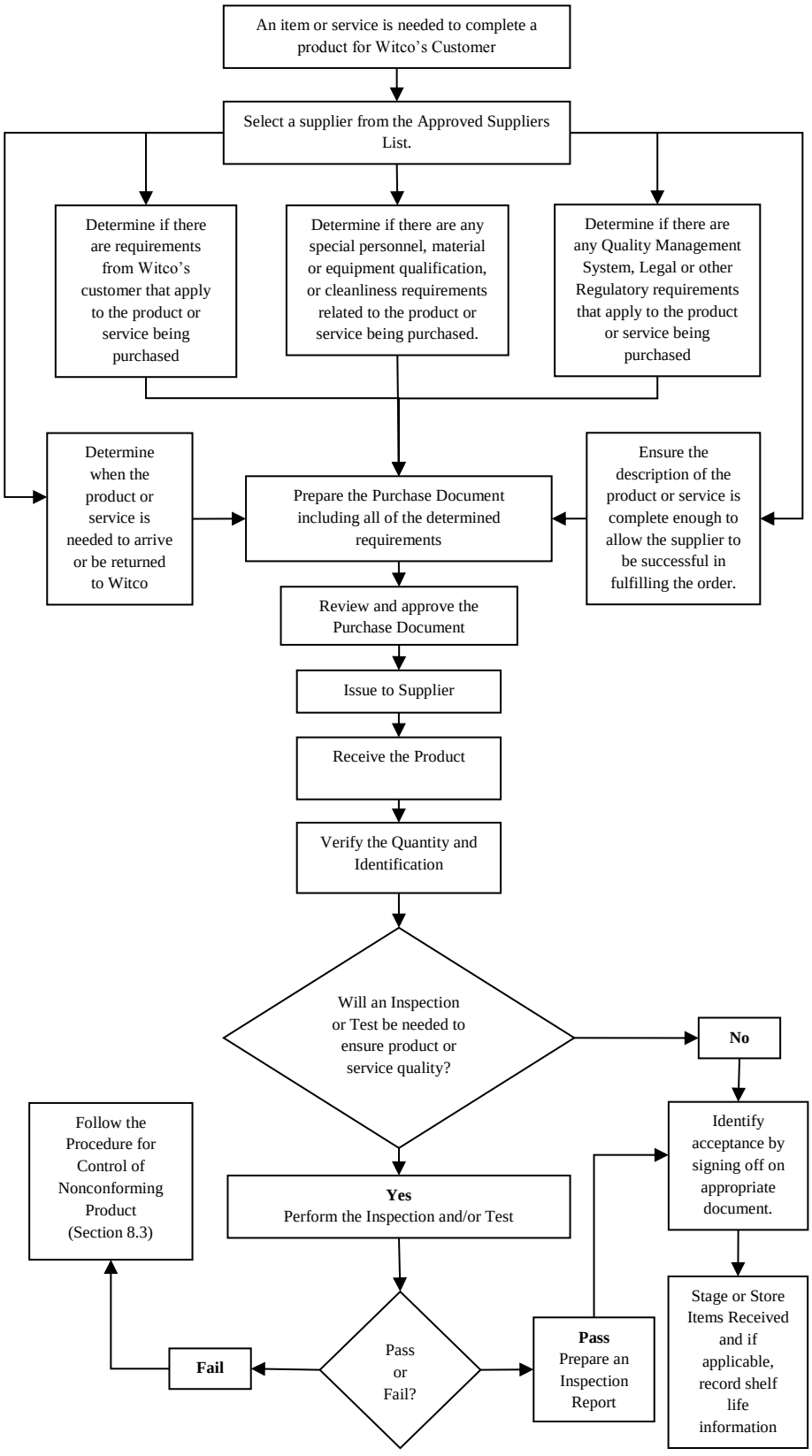
- Risk Assessment
- Shop Paper
- Customer Specifications
- Vendor Quotes

Outputs

- Material
- Services
- Other Resource Needs
- Certifications

Standard Sections to be Audited: 4.2.3, 4.2.4, 7.1.4, 7.4.1, 7.4.2, 7.4.3, 7.5.3, 7.5.5, 8.5.2

Purchasing Process



PEAR #4 Manufacturing

Process Owner: Production Manager

The manufacturing process is responsible for producing and inspecting the product. Calibration, maintenance, inspection and manufacturing engineering lend support to the manufacturing process.

Inputs

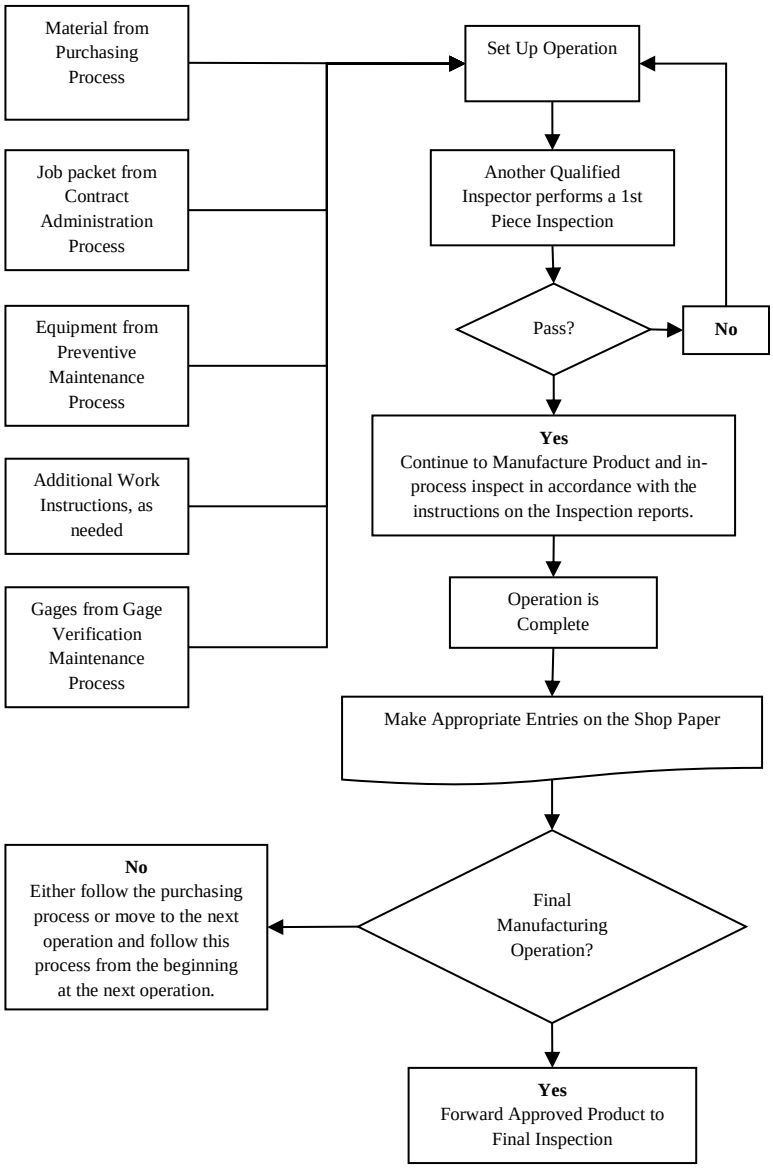
- Risk Assessment
- Customer Specifications
- Shop Paper
- Shop Print
- Process Drawings
- Inspection Reports
- Suggested Gages
- Tool Sheet
- Setup Sheet
- Programs
- Resource Needs

Outputs

- Shop Paper
- Setup Sheets
- Programs
- Inspection Records
- Completed Parts

Standard Sections to be Audited:
4.2.3, 4.2.4, 6.3, 7.1.3, 7.5.1, 7.5.1.1, 7.5.1.2, 7.5.1.3, 7.5.1.4, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.6, 8.2.4, 8.3

Manufacturing Process



PEAR #5 Storage and Shipping

Process Owner: Director of Sales and Marketing

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

Inputs

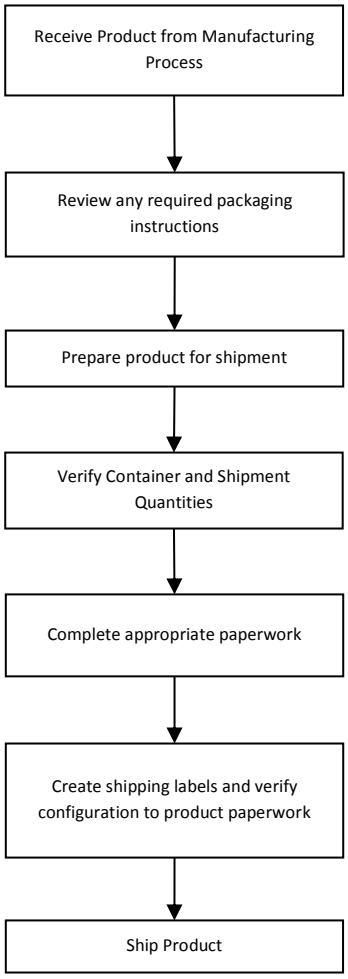
- Confirmed Customer PO
- Sales Order
- Shop Paper
- Special Packaging Requirements (CT-000)
- Completed Parts
- Inspection Records
- Certifications

Outputs

- Shipment Documentation

Standard Sections to be Audited:
4.2.3, 4.2.4, 7.5.3, 7.5.5

Shipping Process

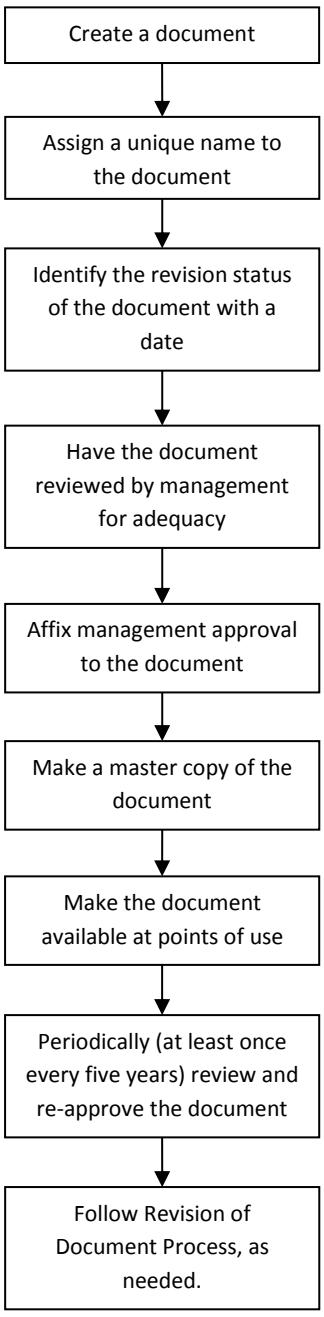


4.2.3 Control of Documents

Documents included in Witco's QMS are controlled.

a) 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.
b) 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.
c) All documents created by Witco will be present in the Master Documents List and shall have a unique title, a visually apparent revision status and identification of the approving authority. The QAF-140, New/Revised Document Request form, will specify changes made to all documents.
d) Users must know where documents are located and how to verify the revision status of those documents. Only the most current revision of a document shall be available through Witco Shop and at its point of use. The user has unrestricted access to the document for the purpose of reading it and its proximity 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.
e) 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.
f) The validity and status of externally controlled documents, including customer drawings, is verified and their distribution controlled as part of the Planning of Product Realization Process (Section 7.1).
g) If necessary, for legal purposes or compliance with customer and/or regulatory agency requirements, obsolete documents may be retained as long as they are identified in a way that makes it visibly apparent and unmistakably clear to the user that the document is obsolete or void, usually a red obsolete stamp. Obsolete documents cannot be used to make decisions regarding compliance for products produced after the document became obsolete.

Control of Documents Process

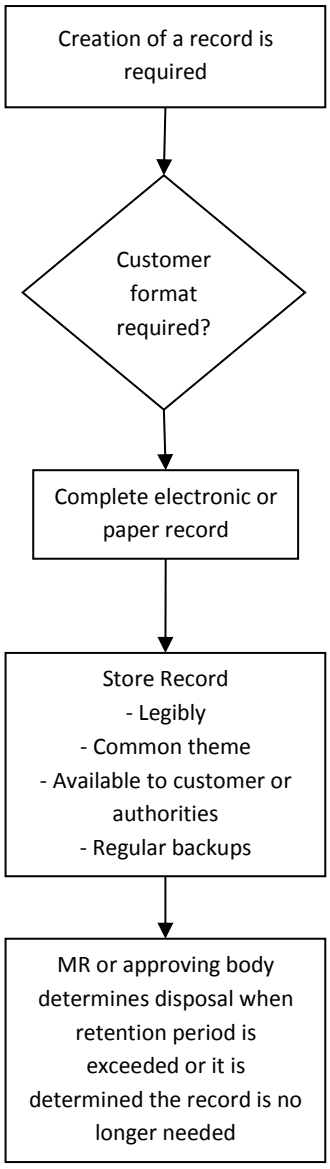


4.2.4 Control of Records

Records that provide evidence of compliance with product realization, the QMS, statutory, regulatory or customer requirements are controlled by this process.

Control of Records Rules
1. The records shall be stored in a manner that is indexed by a common theme. (Customer, job number, date, etc.) 2. Records can be retained on paper or electronic medium. 3. Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements at our facility. 4. Export documentation will be prepared in accordance with statutory and regulatory requirements. 5. Records shall remain legible, readily identifiable, and retrievable. 6. Records will be stored in a manner that preserves their legibility. 7. Electronic records will be stored in an environment that receives regular back up to prevent loss. 8. When required by the customer, their record format will be used in lieu of or in addition to Witco's format. 9. When required, the Management Representative or the individual responsible for approving the document will determine the proper disposal method of records exceeding the retention requirements or at the time it is determined that it is no longer necessary to retain the records.

Control of Records Process



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 and is communicated to the vendor by the Terms & Conditions.

Traceability records come in many forms but are usually located in the Part Folder, JobBoss Windows, JobBoss DOS or Witco Shop.

Emails, Faxes and Letters also serve as records. These are maintained, retained and located according to the type of document they are representing.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management provides evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by

a) communicating the importance of customer, statutory and regulatory requirements through the Quality Policy,
b) establishing, communicating and maintaining Witco's quality policy as put forth in Section 5.3,
c) ensuring that objectives, consistent with the quality policy, are established to ensure the effectiveness of the QMS processes and the conformance of products to their requirements as stated in Section 5.4.1,
d) conducting Management Review Meetings (MRM) at least once each year in accordance with the instructions in Section 5.6.1,
e) ensuring the availability of resources through MRM and Section 6.

5.2 Customer Focus

Top management ensures that all customer requirements are determined and met during product realization, while continuously striving for the highest level of customer satisfaction possible. See Sections 7.2.1 and 8.2.1.

As a minimum, Product Conformity and On-Time Delivery performance are measured to give evidence of customer focus. Witco has assigned all business objectives and KPIs a process effectiveness value which is consistent with the goals of Witco and will maintain customer satisfaction. If process effectiveness values are not met or will not be met, an issue will be entered into the Issues Log and a CA assigned. Reference Section 5.4.1 for business objectives and KPIs.

5.3 Quality Policy

Top management ensures the quality policy

a) is appropriate to Witco's purpose of customer satisfaction,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the QMS,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated through training documents and is publicly posted throughout the facility,
e) is reviewed at each Management Review Meeting (MRM) for continued suitability.

Witco's Quality Policy

The mission of Witco Inc. is to assure a sustainable advantage over our competitors through our dedication, skill and effort to provide complete customer satisfaction by:

- ***successfully employing resources,***
- ***striving for continuous improvement,***
- ***committing total compliance to customer requirements and our Quality Management System***

5.4 Planning

5.4.1 Quality Objectives

Top management has established quality objectives at relevant functions and levels, including those needed to meet requirements for product in Section 7.1 a). Reference the Business Objective & KPI Summary form and inspection reports. All are measurable and consistent with the Quality Policy (Section 5.3).

5.4.2 Quality Management System Planning

Top management ensures that:

a) the planning of the QMS is carried out during MRMs to meet the requirements given in Section 4.1, as well as Witco's Business Objectives and KPI's,
b) the integrity of the QMS is maintained through change control addressed in Section 4.2.3 Control of Documents and Internal Audits.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management established and maintains:

- the Org Chart – Organization Chart without Names that identifies key functions within Witco, including the Management Representative discussed in 5.4.2 and 5.5.2,
- the HRF-190A (Document Training Tracking Grid) which specifies which individuals are:
  - Able to Substitute,
  - Fully Competent, or
  - Able to Train Others,
- the QAWI-90R – Non-conforming Material Disposition Chart which specifies which individuals are required or permitted to disposition non-conforming product and
- the QAWI-90S – Production Process Change Authorization which specifies which positions can make changes to Prints, Drawings, the Shop Paper and Inspection Reports.

The above documents shall be controlled in accordance to 4.2.3 Control of Documents and can be found on the Master Documents List.

5.5.2 Management Representative

Top management has appointed a Management Representative (see Org Chart – Organizational Chart without Names) who has responsibilities and authorities that include:

a) ensuring that processes needed for the QMS are established, implemented and maintained,
b) reporting to top management on the performance of the QMS and any need for improvement,
c) ensuring the promotion of awareness of customer requirements throughout the organization and
d) the organizational freedom to resolve matters pertaining to the QMS.

5.5.3 Internal Communication

Top management ensures QMS effectiveness is communicated by sharing the following information:

- Management Review Meetings (MRM),
- Internal Audit Reports and
- Business Objectives and KPI's.

5.6 Management Review

5.6.1 General

Top management will conduct Management Review Meetings (MRM) at least once each year to ensure the QMS is suitable, adequate and effective. The meetings will include assessing opportunities for improvement and the need for changes to the QMS, including the Quality Policy, Business Objectives and KPI's. These meetings will be recorded in accordance with Section 4.2.4 Control of Records. MRM's may be conducted by one of two methods:

1. Review a log or document to determine if a review input 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.
2. Schedule and conduct a meeting with management personnel to discuss review inputs and determine if a management action should be assigned. The record of this review would be meeting minutes (ADF-70A Witco Inc. Meeting Agenda – Management) that indicates the managers involved, the topics discussed and the actions assigned.

5.6.2 Review Input

The inputs to MRM's include:

a) results of audits,
    a. Internal Audit Reports,
b) customer feedback,
    a. Issues Log
c) process performance and product conformity,
    a. Business Objectives and KPI Summary and Charts – Issues Log.
d) status of preventative and corrective actions,
    a. Issues Log
e) follow-up actions from previous MRM's,
    a. Previous MRM's Minutes – These are actions assigned from previous meetings. They are reviewed to determine if they have been completed and effectively accomplished their purpose.
f) changes that could affect the QMS, and
    a. Managerial Input – this information can be obtained from internal audits, employee suggestion, etc.
    b. This includes revisions to the QMS 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.
g) recommendations for improvement.
    a. Managerial Input – this information can be obtained from internal audits, employee suggestion, etc.

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.

5.6.3 Review Output

The outputs of MRM's include decisions or actions related to:

a) improvement of the effectiveness of the QMS and it's processes,
b) improvement of product related to customer requirements, and
c) resource needs.

Any decisions made during the meeting, assigned actions and their due date are recorded in the MR Meeting minutes (ADF-70A).

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

Witco has determined that human and infrastructure resources are needed to maintain the QMS and continuously improve its effectiveness to enhance customer satisfaction. We provide these resources through the Planning of Product Realization Process and Management Review Meetings (MRMs) and ensure satisfaction by reviewing Business Objectives and KPI's.

6.2 Human Resources

6.2.1 General

Witco ensures that personnel performing work that affects product conformity will be competent on the basis of education, training, skill and experience.

6.2.2 Competence, Training and Awareness

Witco:

a) has created HRF-190A, the Document Training Tracking Grid, which lists the necessary qualifications required of positions that affect conformity to product,
b) continuously provides training through the QMS Manual and other documentation to ensure all employees achieve the necessary level of competence,
c) evaluates the effectiveness of employee training through review of Employee Competency issues during MRMs and employee performance reviews,
d) posts quality objectives throughout the facility so employees can be aware of the importance and their relevance to the contribution of the objective's achievement,
e) maintains records according to Section 4.2.4 in the Human Resource Office as evidence of employees education, training, skill and experience.

HRF-190A Document Training Tracking Grid
The Document Training Tracking Grid 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.

6.3 Infrastructure

Witco determines, through MRM's and the Planning of Product Realization Process, and provides and maintains through the Preventative Maintenance Schedule, an infrastructure needed to achieve conformity to product requirements.

6.4 Work Environment

Witco manages the work environment needed to achieve product conformity through Management Review (Section 5.6), Risk Management (Section 7.1.2), Work Center Audits and employee suggestions.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

Witco conducts planning before new products or processes are implemented. During this planning, assigned personnel identify:

a) quality objectives and requirements of the product, including, but not limited to, safety, availability, producibility, and inspectability,
b) product specific processes, documents and resources,
c) verification, validation, monitoring, measurement, inspection/test activities and criteria for product acceptance,
d) the records needed to provide evidence the realization process and resulting product meet requirements in accordance with Section 4.2.4,
e) appropriate configuration management in accordance with Section 7.1.3, and
f) the resources needed to support the use and maintenance of the product.

The output of this planning is the Shop Paper, Shop Print, Process Drawings, Tool Sheets, resource expectations, Inspection Reports, Suggested Gage forms and special packaging requirements.

Planning of Product Realization Process
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)

7.1.1 Project Management

Witco plans and manages product realization in a structured and controlled manner so requirements are met at acceptable risk and within resource and schedule constraints utilizing Section 7.1.2 Risk Management.

7.1.2 Risk Management

Witco established, implemented and continuously maintains the Risk Assessment process in Witco Shop for managing risk to the achievement of applicable requirements, including:

a) assignment of responsibilities,
b) the definition of risk criteria,
c) the identification, assessment and communication of risks,
d) identification, implementation and management of actions to mitigate risks that exceed the acceptance criteria, and
e) acceptance of risks remaining after implementation of mitigating actions.

Risk is assessed by the Sales Engineer during the Contract Administration Process. High risk projects may require extraordinary measures to ensure customer requirements are met and if after assessing the risk drivers, it is determined that measures are needed to mitigate the risks an Issue will be created in the Issues Log. Risks are identified even if “No Risk” is the identifying communication. If requirements cannot be met, Witco will attempt to resolve them with the customer or decline the offer to quote.

As part of reviewing a contract, risk factors must be considered. Risk factors are located in the "Risk Type" drop down on the Risk Assessment PO tab in Witco Shop.

These requirements will be communicated to the planning process for incorporation into appropriate scheduling and manufacturing instructions.

7.1.3 Configuration Management

Witco is not the design authority for the products they produce. However, Witco has established, implemented and continuously maintains a configuration management process that includes:

a) a configuration management plan that includes verification of engineering revision levels during the Contract Administration Process,
b) identification of part and process engineering revision levels on all documents, records and labels, including the presence of the part engineering revision level on the process drawing throughout processing,
c) change control that must be approved by the customer and when it is, nonconforming product will be processed in accordance with Section 8.3 Control of Nonconforming Product,
d) configuration status accounting is satisfied in sub-clause a) above, and
e) auditing of the part and process engineering revision levels at the creation of the job packet, at packaging, during Work Center Audits and appropriate Internal Audits where revision levels of finished goods inventory will also be verified.

Finished goods labels must include the engineering change level.

7.1.4 Control of Work Transfers

Work transferred from Witco to Supplier or Supplier to Supplier will be controlled by the Purchasing Process. Once work transferred is complete and returned to Witco, it will be inspected per Section 7.4.3 Verification of Purchased Product to verify conformance to specifications.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Witco determines customer requirements before acceptance of an order during the Contract Administration Process and will:

a) consider all customer requirements including delivery and post-delivery activities,
b) confirm the customer's requirements on key characteristics prior to acceptance if the customer does not provide a clear description of the product or requirements,

c) adhere to any statutory or regulatory requirements applicable to the product, and
d) any additional requirements determined necessary.

7.2.2 Review of Requirements Related to the Product

Witco reviews the requirements related to the product prior to committing to supply said product to the customer during the Contract Administration Process. Witco ensures that:

a) product requirements are defined through assessment of the customer supplied print, customer purchase order and other relevant customer communication,
b) any requirement changes that have occurred from previously expressed requirements are resolved by communication with the customer and documented appropriately,
c) they have the ability to meet the defined requirements,
d) special requirements of the product are determined and documented in the appropriate location, and
e) risks are identified through Section 7.1.2 Risk Assessment.

Records of the results of the review and actions arising from the review will be maintained per Section 4.2.4 Control of Records.

When the customer provides no documented statement of requirement, the Sales Engineer will communicate with the customer, confirm their requirements and document the findings in the appropriate location.

When product requirements change, the Sales Engineer will update the relevant documents and forward these changes to Planning.

7.2.3 Customer Communication

Witco has determined that verbal and written communication is an effective arrangement for communicating with customers in relation to:

a) product information,
b) request for quotation, contracts or authorizations to proceed, including amendments and if the customer requires a specific format, that format will be used, and
c) customer feedback, including customer complaints which are entered into the Issues Log for management review.

7.3 Design and Development

Exclusions from AS9100, ISO13485 or ISO9001 and Justification for Exclusion:

Clause	Topic	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.

7.4 Purchasing

7.4.1 Purchasing Process

Witco ensures that purchased product conforms to specified purchase requirements. The type and extent of supplier and product control is dependent on the effect of the purchased product in subsequent product realization stages or the final product.

Witco is responsible for the conformity of all products purchased from suppliers, including those from sources determined by the customer.

Witco evaluates and selects suppliers based on the Supplier Approval and Monitoring Instruction below. Records of the results of these evaluations and actions taken will be maintained in accordance with 4.2.4 Control of Records.

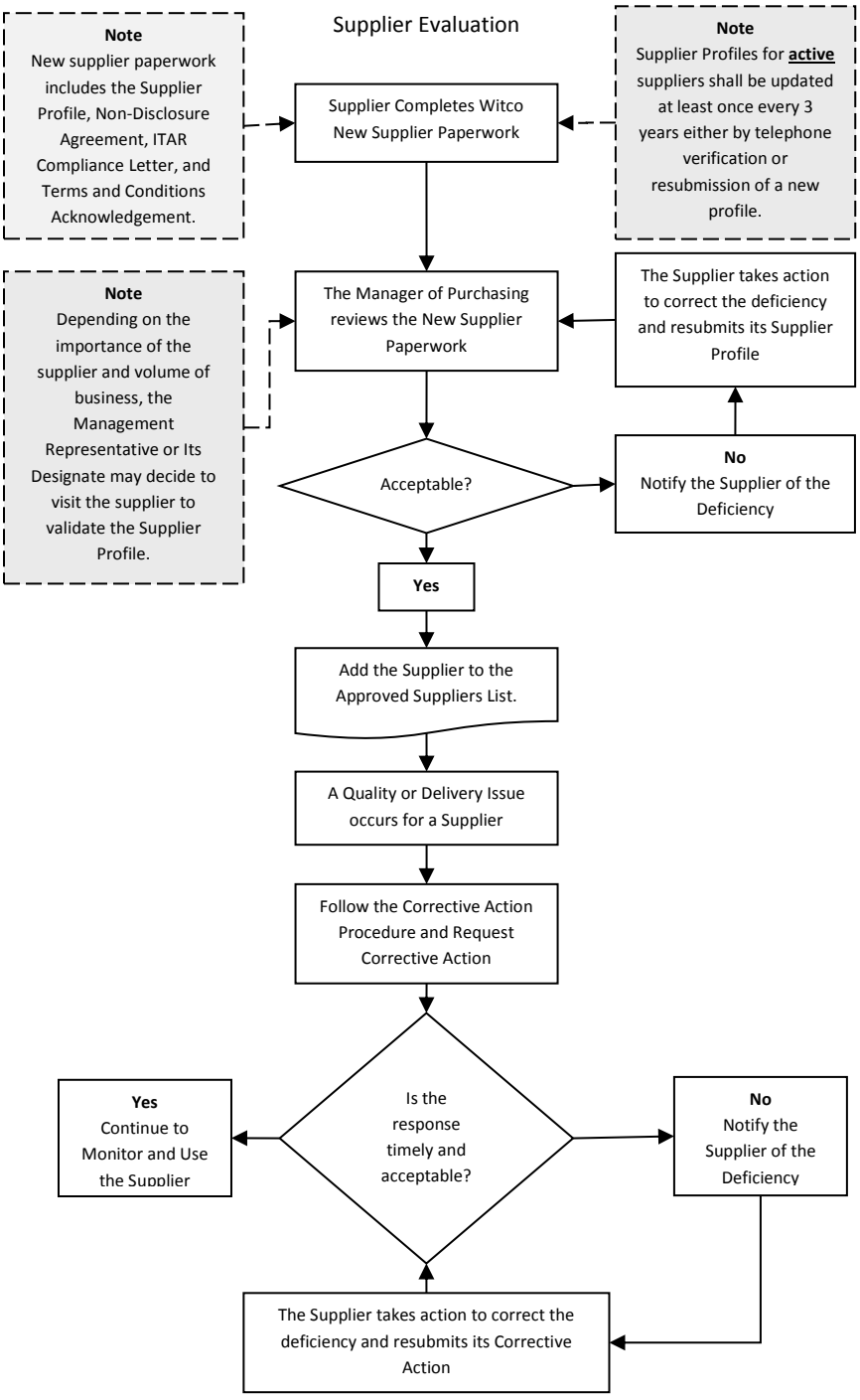
Witco:

a) maintains the Approved Suppliers list in Witco Shop that includes the scope of the supplier and its approval status,
b) reviews supplier performance using Business Objectives and KPIs which are used as a basis for control levels,
c) will create a supplier NCM in Witco Shop and may issue corrective actions to suppliers who fail to meet performance requirements. Continual failure will make the supplier subject to being placed on “Inactive” status and a search for a replacement supplier will begin. Suppliers that refuse to respond to a Corrective Action Request are subjects for “Inactive” status and eventual replacement,
d) ensures that customer approved special process sources are used when required by communicating that information on the Shop Paper,
e) defines the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier’s approval status according to the Supplier Approval and Monitoring Instruction below, and

f) determine and manage the risk when selecting and using suppliers through the Supplier Profile form that is filled out by each supplier before being placed on the Approved Suppliers list and, at a minimum, every 3 years after.

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 finished product **must** complete the Supplier Profile. Suppliers will also be asked to complete the Non-Disclosure Agreement, ITAR Compliance Letter and the Terms and Conditions Acknowledgement. The completion of these three documents is not required but can play a part in receiving approved status. The Director of Sales and Marketing or a Management Representative must approve a supplier prior to the issuance of a purchase order, except in emergency purchases. 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 procuring the product or service which is not preferred to purchase 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. 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. Suppliers are evaluated continually and may be placed on “Inactive” status at any time at the discretion of the Management Representative. All non-conformances, including late deliveries, are documented on a Corrective Action Request at the discretion of a Management Representative. 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. The Director of Sales and Marketing and the Management Representative have the ability to disapprove or inactivate a supplier at any time and for any reason.

Supplier Evaluation Process



7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including, where appropriate

a) the requirements for approval of product, procedures, processes and equipment which are located on the purchase order or drawing,
b) the requirements for qualification of personnel which are noted on the purchase order,
c) quality management system requirements which are noted on the purchase order,
d) the identification and revision status of the part including drawings, purchase orders, and inspection reports as applicable,
e) requirements for design, test, inspection, verification, use of statistical techniques for product acceptance and related instructions for acceptance by the organization and as applicable critical items including key characteristics which are noted on the purchase order or a separate document attached to the purchase order,
f) requirements for test specimens for design approval, inspection/verification, investigation or auditing which are noted on the purchase order or a separate document attached to the purchase order,
g) requirements regarding the need for the supplier to
   - notify the organization of nonconforming product,
   - obtain organization approval for nonconforming product disposition,
   - notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and where required, obtain organization approval, and
   - flow down to the supply chain the applicable requirements including customer requirements

   which are present on the purchase order and/or located in Witco's Terms & Conditions, which is referenced on all purchase orders,
h) record retention requirements which would be noted on Witco's purchase order, and
i) right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records which is stated in Witco's Terms & Conditions and referenced on all purchase orders.

Purchasing documents are reviewed, initialed and dated for adequacy before they are communicated to the supplier.

7.4.3 Verification of Purchased Product

Witco conducts receiving inspections or obtains objective evidence from the supplier (certification of conformity, test records, etc.) when product is received to ensure purchased products/services meet specified purchase requirements.

When a test certificate is required and received with the material, it shall be reviewed, indicate the reviewer and filed with the customer purchase order. The review will be to ensure that it indicates proper compliance and bears an authorized signature.

When purchased product is released for production use without verification, the Shop Paper will be noted appropriately to allow for recall and replacement if later it is determined that product doesn't meet requirements.

Witco will note the purchase order when they delegate verification activities to the supplier. Copies of these PO's will be kept in a folder on the Buyer's desk as a register of these delegations.

If Witco or her customer intends to perform verification at the supplier's premises, they will state the intended verification arrangements and method of product release on the purchase order.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Witco uses a Job Packet to plan and carry out production and service provision under controlled conditions, including:

a) customer prints, process drawings and the Shop Paper which describes the characteristics of the product,
b) customer prints, process drawings, the Shop Paper, setup sheets, inspection reports and suggested gage forms which serve as work instructions,
c) setup sheets and programs which spell out suitable equipment,
d) suggested gage forms for monitoring and measuring equipment,
e) inspection reports for the implementation of monitoring and measurement,
f) the Shop Paper and sales order for implementation of release, delivery and post-delivery activities,
g) the Shop Paper, Material Hold Tag, Parts Sign-Out Form and Outsourced Parts Sign-Out form which allows for accountability of all product during production. Shipping accounts for all parts before closing the job.
h) Shop Paper sign off and inspection report completion serve as evidence that production and inspection/verification operations have been completed as planned or as otherwise documented and authorized,
i) the HRWI-360 Foreign Object Debris Prevention Program for the prevention, detection and removal of foreign objects,
j) the Shop Paper or setup sheets will instruct individuals appropriately so utilities and supplies can be monitored and controlled, and
k) the Shop Paper and First Piece sample (if applicable) which define any criteria for workmanship.

The above information will be accessible at point of use as needed.

Planning considers, as appropriate

- customer recognized key characteristics which are segregated from the other general specifications and assigned a C=0, 1.00% AQL frequency check on inspection reports,
- the use of gages to measure variable data,
- inspection/verification points using C=0, 10.00% AQL frequency checks and identifying when verification of conformance cannot be performed at later stages of realization, and
- special processes (section 7.5.2).

7.5.1.1 Production Process Verification

Production process verification shall be performed as required by the customer on a completed product from the first production run. If a change is made to the equipment, material, process, work instruction or the supplier used to perform the production process verification, a 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.

Production Process Verification Process (First Article Inspection):
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.

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes have been identified in QAWI-90S, Production Process Change Authorization.

Witco controls and documents changes affecting processes, production equipment, tools or software programs on the appropriate documents in accordance with section 4.2.3 Control of Documents.

The results of changes to production processes are assessed at inspection to confirm that the desired effects have been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs are validated prior to use during first piece inspection (see section 8.2.4) and records maintained according section 4.2.4 Control of Records.

Production equipment essential to product quality and delivery receive preventive maintenance based on their type, importance, need, automated warning capability, disposable value and management review (Issue #2931). 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.

Programs created from software for the control of manufacturing and/or inspection operations shall be controlled in accordance with section 4.2.3 Control of Documents. The identification of these programs shall also reference the engineering change status of the product for which it was created.

7.5.1.4 Post-Delivery Support

Post-delivery support will provide as needed

a) the collection and analysis of in-service data as requested by the customer,
b) the actions to be taken, including investigation and reporting, when problems are detected after delivery which are determined during the Corrective Action process (section 8.5.2),
c) control and updating of technical documentation which is determined during the Corrective Action process (section 8.5.2) and effectiveness audited,
d) approval, control and use of repair schemes, and
e) the need for, controls and individuals qualified to perform off-site work are determined by the Management Representative, Director of Sales and Marketing and the Engineering Manager based on the nature of the work to be completed.

7.5.2 Validation of Processes for Production and Service Provision (Special Processes)

Witco validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered through sections 7.4.2 Purchasing Information and 7.4.3 Verification of Purchased Product.

Vendor validation will demonstrate the ability of these processes to achieve planned results.

Witco will, as needed, supply vendors with a Shop Print, Process Drawing or written instruction on the purchase order to establish arrangements for special processes including, as applicable,

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (section 4.2.4), and
e) revalidation.

7.5.3 Identification and Traceability

Witco uses the Shop Paper, Box Tickets, OK for Next Process, Approved 1st Piece, Material Hold, Material Inventory Tags, etc. for identification throughout product realization. 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.

A Material Hold Tag and/or Non-Conforming Material Report will be used to identify any differences between the actual configuration and the agreed configuration.

The Shop Paper, Inspection Reports and Box Tickets report the status of the product in respect to monitoring and measurement.

Witco only issues acceptance authority media (stamps, passwords, etc.) to those individuals authorized to use it. See QAWI-90S Production Process Change Authorization and QAWI-90R Non-Conforming Material Disposition Chart.

Witco will control the unique identification of product on a case by case basis when instructed by the customer to do so. Records will be maintained according to section 4.2.4 Control of Records.

Product packaged for storage will be identified with a packaging date.

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 identification number from the certification and may not be mixed in the same container.

7.5.4 Customer Property

Witco will exercise care when customer property is being used or in their care. Customer property will be identified utilizing an SRF-80 Internal Receiver (Customer), verified for damage and adequacy upon receipt, and protected and safeguarded appropriately for the type of property and its application. Issues with customer supplied items shall be reported to the customer for disposition and documented according to Section 4.2.4 Control of Records.

7.5.5 Preservation of Product

Witco will preserve product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation includes, when applicable, identification of the product using the forms referenced in section 7.5.3 Identification and Traceability and common industry methods for handling, packaging, storage and protection. This process will also apply to the constituent parts of a product.

Witco will utilize industry standard methods for preservation of product and, where applicable, note customer, statutory and regulatory specific requirements on the Shop Print, Process Drawings, Shop Paper or flowed down to suppliers on Witco's purchase order, including,

a) cleaning,
b) prevention, detection and removal of foreign objects,
c) special handling for sensitive products,
d) marking and labeling including safety warnings,
e) shelf life control and stock rotation, and
    a. Finished Goods box label identified with package date.
f) special handling for hazardous materials.

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

Product will be stored and shipped in a manner that prevents contamination from foreign objects and debris.

7.6 Control of Monitoring and Measuring Equipment

Witco will use the customer supplied print (Shop Print) to determine the monitoring and measurement to be undertaken and the Suggested Gages form to determine the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. 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 1/10th 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, it will be verified using standards traceable to international or national standards.

Witco maintains a register of the monitoring and measuring equipment, including employee owned and customer supplied, and defines the process employed for their calibration/verification including details of equipment type, unique identification number, location, frequency of checks, check method and acceptance criteria.

Gages identified as "Reference Only" cannot be used to accept or reject product.

Witco has established processes in the Planning of Product Realization Process (section 7.1) and section 8.2.4 Monitoring and Measuring of Product to ensure that monitoring and measurement can be carried out and is carried out in a manner that is consistent with the monitoring and measurement requirements.

Witco ensures environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out by maintaining a temperature condition log with the optimal temperature being 68°F, ±5°F.

Witco's measuring equipment will, when necessary to ensure valid results,

a) be calibrated or verified using intervals that are based on history or adjustment, accuracy required and working environment and are documented or verified "prior to use" using the National Institute of Standards and Technology. When this standard isn't applicable, the basis used for calibration or verification will be recorded in accordance with section 4.2.4 Control of Records,
b) be adjusted or readjusted if suspect conditions, including accidental impact (bumping or dropping) lead the gage user to believe readings could be invalidated,

c) be identified legibly and conspicuously, either on the equipment or equipment container, with a gage number so calibration status can be validated,
d) be safeguarded from adjustments that would invalidate the measurement result during gage setup, 1st Piece Inspection, floor audits and morning checks,
e) be protected from damage and deterioration during handling, maintenance and storage by the individual using the gage.

At a minimum of once per month, the Quality Assurance Department will run a report showing which equipment is due for that month for calibration. The same department will coordinate the recall of the equipment due and perform the calibration of these devices.

When equipment is found not to conform to requirements, Witco will assess and record the validity of the previous measuring results. The equipment will be taken out of production use and appropriate disposition of the equipment and product will be conducted. 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.).

Records of the results of calibration and verification are maintained according to section 4.2.4 Control of Records. Records will include:

- Type of Equipment
- Equipment ID Number
- Location
- Calibration Date & Next Calibration Due Date
- Acceptance Criteria
- Identity of Calibrator

Witco confirms the ability of its computer software's to satisfy the intended application during initial research of the software and it's reconfirmed during the Internal Audit Process.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Witco plans and implements the monitoring, measurement, analysis and improvement processes needed,

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the QMS and
c) to continually improve the effectiveness of the QMS system,

through inspection report records, Business Objectives (section 5.4.1), KPIs (section 5.4.1), the Issues Log (product conformity, corrective action, preventive action, customer feedback, supplier quality problems and internal issues that can affect process performance), Management Review (section 5.6), Internal Auditing process (section 8.2.2), Corrective Action process (section 8.5.2) and Preventative Action (section 8.5.3) processes.

Determining applicable methods of monitoring, measuring, analyzing and improving and the extent of their use is widely customer based, including the C = 0 sampling plan.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As a measurement of the performance of the QMS, Witco monitors information relating to customer perception as to whether we have met customer requirements through the Customer Return and Customer Complaint issue categories documented in the Issues Log.

At a minimum, Witco will monitor product conformity (Cost of NCMs), on-time delivery performance (Witco On-Time Delivery), customer complaints (Customer Complaints) and corrective action requests (Customer Returns). We utilize the Management Review (section 5.6) and the Corrective Action (section 8.5.2) processes to develop and implement plans for customer satisfaction improvement that address the deficiencies identified by these evaluations and assess the effectiveness of the results through CA/PA audits and the Internal Audit process (section 8.2.2).

8.2.2 Internal Audit

Witco conducts internal audits in accordance to the Audit Schedule documented in Witco Shop to determine whether the QMS

a) conforms to the planned arrangements to the requirements of both the International standard and to the QMS established by Witco, and
b) is effectively implemented and maintained.

The Management Representative (MR) creates the Internal Audit Schedule annually in Witco Shop, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The Internal Audit Schedule defines the audit criteria and scope. The MR selects auditors and conducts audits to ensure objectivity and impartiality and ensures the audits are conducted in a timely manner. Auditors will not audit their own completed work in this section, 8.2.2, or any other section they may be involved with in this QMS Manual.

Auditor Selection

- Witco Internal Auditors: Must have at least 6 months of experience at Witco and be trained by a Certified Quality Auditor on section 8.2.2 Internal Audit. Internal auditors are required to complete at least one audit per 12 month period between 3rd party surveillance audits.
- Outside Agency: An outside agency can be contracted to perform the internal audits. They must be certified to an AS/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 nonconformances found
  - The audit scope and results

Conducting the Audit

The audit is conducted using one of three methods:

- Observation: Auditing by observation requires observing the process in action and noting whether or not it is compliant, effective and efficient.
- 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 section 4.2.4 Control of Records.
- 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.

Internal Auditing Procedure
1. An Internal Auditor (IA) has an audit that requires completion. 2. The IA obtains an audit worksheet, a copy of the most recent standard and Witco's most recent QMS Manual. 3. The IA conducts the audit using an approved method and documents the evidence. 4. Supporting processes and sections shall be audited as part of the core processes they support. 5. The IA determines if each audit line passes or fails (findings) in regards to both the standard and the QMS Manual. 6. A Corrective Action is automatically created if a section has findings in either the standard or the manual.

The Audit Worksheet and Audit Report records will be stored in Witco Shop according to section 4.2.4 Control of Records.

Internal audit findings automatically create a corrective action issue in the Issues Log and assigns the Process Owner and a resolution due date. The resolution of this issue should indicate systemic action. All corrective action issues will automatically create an audit upon resolution so verification of the actions taken and the reporting of verification results taken can be assessed.

8.2.3 Monitoring and Measurement of Processes

Each of Witco's five QMS processes will be monitored and measured through Key Performance Indicators (KPIs). Each KPI will have a Process Effectiveness Goal and when the goal is not met, a corrective action will be created in the Issues Log. These objectives can be located on the Business Objectives and KPI Summary worksheet.

In the event of process nonconformity, Witco will

a) create a corrective action issue in the Issues Log,
b) determine if the process nonconformity resulted in product nonconformity
c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
d) identify and control any nonconforming product per section 8.3 Control of Nonconforming Product.

8.2.4 Monitoring and Measurement of Product

Measurement requirements for product acceptance are documented and include

a) inspection reports (created from Shop Print and/or Process Drawings) that determine acceptance and rejection criteria,
b) training (see below) and frequency on inspection reports,
c) inspection reports as records of measurement results and
d) the Suggested Gages form that specifies required measurement instruments and any relevant instructions for their use.

Inspection Types

First Piece Inspections

- 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 setup 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 the process. If the customer dictates batch/lot requirements, the

original First Piece can be shipped with the appropriate batch. A production part can take the place of the First Piece if the QAF-004 Approved 1st Piece tag noted "Workmanship Part".

- First piece approval shall be documented on the Shop Paper and inspection report.

In Process Inspections

- Additional inspections are performed by the process operator and documented in accordance with the instructions on the inspection report.

Receiving Inspections

- See section 7.4.3 Verification of Purchased Product.

Final Inspections

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

There are 2 processes that control and monitor critical items when identified.

- Critical/Key Characteristics: Designated by the customer, critical/key characteristics are located on inspection reports along with an AQL Level 1.0 inspection frequency. The record must identify the inspector, the part number and engineering change level.
- High Risk: These critical items are determined during 7.1.2 Risk Management and a High Risk issue is created in the Issues Log. Resolution must be applied to the issue.

Sampling Instruction
A sample of product in accordance with the C = 0 sample plan is inspected. As a minimum, the critical/key characteristics are inspected.

The sampling table represents a C = 0 sampling plan and shall be used when 100% inspection is not practical or required. Unless otherwise indicated, 1.0% AQL is used as a minimum for customer designated critical/key characteristics and 10.0% AQL is used for all general characteristics. In process inspections may be designated as a rate (i.e. "x per hour", "every 10th part", etc.). The rate should satisfy the sample size indicated in the sampling table.

Customer requirements take precedent over Witco's sample designations.

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

Where product is released for production use pending completion of all required measurement and monitoring activities, it will be identified and recorded in the inspection records in Witco Shop to allow recall and replacement if it is subsequently found that the product does not meet requirements.
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. The CT-000 line on the Shop Paper will include the initials of the person authorizing release of product for delivery to the customer and this record will be controlled through Section 4.2.4 Control of Records.

Witco provides inspection reports, QAF-20 Certificate of Compliance to Customer Specification, Supplier Certifications and Test Results and other documentation, when applicable, to provide evidence that product meets defined requirements.

Unless otherwise approved by a relevant authority or customer, Witco will not release product to final shipment without completing the planned arrangement set out in Section 7.1 Planning of Product Realization.

Customer required documents will accompany the shipment of product unless other plans were requested by the customer (i.e. electronically before the shipment arrives).

8.3 Control of Nonconforming Product

The Control of Nonconforming Product procedure covers product that is unexpectedly nonconforming. It does not include, with the exception of identity and segregation requirements, anticipated nonconformances such as set up scrap. This procedure may not apply to nonconformances found and corrected in the process in which they were created.

Witco will ensure that non-conforming product is identified and controlled to prevent its unintended use or delivery.

- The product or its container shall be clearly identified as nonconforming. When identifying a container, the identification shall indicate the quantity of parts.
- The identification shall usually be a QAF-002 Material Hold Tag that identifies the part number and where applicable, job or lot number of the nonconforming product.
- Records must indicate the person, customer or outside agency that has classified the product(s) as nonconforming.
- Product identified as scrap shall be permanently and conspicuously identified until it can be rendered unusable.

Responsibility and Authority
Dispositions can only be completed by approved individuals. The Master Documents List contains form QAWI-90R Nonconforming 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 QAWI-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 QAWI-90R form (either at New Hire Orientation or through additional continual improvement training).

- **Scrap** – Product deemed scrap must be permanently and conspicuously identified, stored in a separate container, and accompanied with a Material Hold Tag (QAF-002). If a Scrap part can be used as a setup piece on a subsequent process it is acceptable to move forward but must be identified as a scrap setup piece. 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 and stapled to the back of the Shop Paper. Scrap material will be rendered unusable and disposed of.

  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 then be removed from the Shop Paper and discarded.

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

- **Repair** – If the product is to be repaired, a waiver request will be initiated to obtain a customer approved repair method to be employed by Witco. Repaired product should be given a unique package and identification during the shipping process.

- **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.

- **Ok to Proceed** – Indicates that a nonconformance 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 nonconformance is on an internal process, a waiver request will not be initiated and OK to Proceed will be authorized using QAWI-90R Non-Conforming Material Disposition Chart). Once the Design Authority has approved the waiver, the disposition can be completed and the parts can be moved to the next process.

Where applicable, Witco will deal with nonconforming product by one or more of the following ways:

a) Taking action to eliminate the detected non-conformity.
b) Authorizing its use, release or acceptance under concession by a relevant authority and/or customer.
c) Taking action to preclude its original intended use or application.
   Segregation – Nonconforming product shall be moved to a location where it cannot easily be mixed or confused with conforming product.
d) Taking action appropriate to the effect, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started (see Containment section below)
e) By taking action necessary to contain the effect of the nonconformity on other processes or products.

Containment

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

- Check for additional nonconforming product still in processes or inventory.
- Institute a 100% inspection requirement until the cause of the nonconformity can be eliminated.

- Notify, in a timely manner any concerned parties (e.g. customer or supplier) if it is suspected that nonconforming product has been shipped.

Management may notify the customer of a nonconformance if it cannot be reworked by Witco. The customer or design organization 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 if the nonconformity results in a departure from the contract requirements. Product dispositioned as scrap will be handled utilizing the Scrap section above.

Nonconforming product will be subjected to re-verification to demonstrate conformity utilizing the First Piece Inspection and Final Inspection processes spelled out in section 8.2.4 Monitoring and Measurement of Product.

Records will be maintained for incidents that result in the creation of unanticipated nonconforming parts through the Issues Log for management evaluation (see section 4.2.4 Control of Records).

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.

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 (below), c. Follow the procedure in section 8.5.2 Corrective Action. 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.

Internal Nonconformance
1. Contact customer and inform them of nonconformance. 2. Identify the product and segregate it from conforming product. 3. Notify management and enter into the Issues Log. 4. Obtain a disposition. 5. Execute the disposition.

8.4 Analysis of Data

Witco collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.

- Monthly review of Business Objectives and KPIs.
- Review of the Internal Audits and Corrective Actions during Management Review (electronic).

Witco's analysis of data provides information relating to

a) customer satisfaction from section 8.2.1
b) conformity to product requirements from section 8.2.4
c) characteristics and trends of process and products, including opportunities for preventive action from section 8.2.3 Monitoring and Measurement of Processes and 8.2.4 Monitoring and Measurement of Product
d) suppliers from section 7.4 Purchasing.

8.5 Improvement

8.5.1 Continual Improvement

Witco continuously improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Witco monitors the implementation of improvement activities through the Issues Log and evaluates the effectiveness of the results through audits automatically assigned to Corrective and Preventative Action issues.

8.5.2 Corrective Action

The purpose of this procedure is to identify the causes of nonconformity and correct those causes to prevent the occurrence of similar nonconformities in the future.

The Management Representative (MR) is responsible for coordinating corrective action activities.

This procedure will be applied to all customer returns and to other nonconformities at the discretion of Witco's management.

A documented procedure has been established to define requirements for

a) reviewing nonconformities,
    a. Management reviews the Issues Log, which includes customer returns, for potential corrective action activity.
b) determining the causes of nonconformities,

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

   The following questions may be asked in the investigation of the root cause of nonconformity:
   - Is employee training required?
   - Is there a material or supplier problem?
   - Are the work instructions clear?
   - Are the measuring methods adequate?
   - Is there evidence of an equipment problem?
   - Is the workspace where the nonconformity occurred conducive to a quality product?
   - Are there sufficient resources to produce conforming product?
   - Is Witco capable of producing conforming product?

c) evaluating the need for action to ensure that nonconformities do not recur,
   a. 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.

d) determining and implementing action needed,
   a. Action must be taken in potentially three different areas:
      i. Action to correct the nonconformity.
      ii. Action to correct the cause of the nonconformity.
      iii. If the nonconformity was discovered by the customer, action must be taken to correct the problem with detection of the nonconformity prior to shipment.

e) records of the results of action taken (see 4.2.4),
   a. All Corrective Action Requests (CARs) are to be entered into the Issues Log. QAF-10 Corrective Action Request Form may be used to document and facilitate the Corrective Action process and used for reference material.

f) reviewing the effectiveness of the corrective action taken,
   a. All CARs are entered into the Issues Log and 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 (flag for next run). 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.

g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity.
    a. If a supplier was the cause of the nonconformance, the corrective action activity may be flowed down to the supplier by initiating a QAF-10 Corrective Action Request.
h) specific actions where timely and/or effective corrective actions are not achieved, and
    a. 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. If CARs are not answered in a timely fashion, the MR will call an emergency MRM for immediate closure of the CAR.
    b. Ineffective CARs will be handled according to 8.5.2 f).
i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.
    a. Another cause may be identified when investigating the root cause that is not the cause of the specific nonconformity being investigated. In this instance, a new issue will be created and the cause should be considered for preventive action.

8.5.3 Preventative Action

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

Witco has determined action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventative actions are appropriate to the effects of the potential problems.

The Preventative Action procedure defines requirements for

a) determining potential nonconformities and their cause,
    a. The need for preventive action may be identified from several sources which include, but are not limited to:
        - Management Review Meetings
        - Internal Audit
        - Customer Complaints
        - Employee Complaints or Suggestions
        - Product Realization Planning
        - Risk Management
        - Changes in Customer Requirements
        - Reduction of Resources
b) evaluating the need for action to prevent occurrence of nonconformities,
    a. Witco will consider the value of taking actions to eliminate potential nonconformities. Customer satisfaction shall be given extra weight in the consideration of value.
c) determining and implementing action needed,

a. 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

d) records of results of action taken (see 4.2.4), and
   a. 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 Action being completed.

e) reviewing the effectiveness of the preventative action taken.
   a. 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.

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 section 8.5.2 Corrective Action, as necessary.

The Issues Log can be used to gather information on product nonconformance found internally, customer complaints, failure to meet the customer’s delivery requirements, product returns related to problems caused by Witco or its supplier, nonconformance 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.