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Quality Management System Manual

Revision W

Certified to AS9100 Revision D

Table of Contents

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.
N	4-20-16	Updated the Manufacturing Process flow chart, revised the wording in section 4.2.3 for clarification purposes, added the determination of packaging requirements to the Planning of Product Realization

		Process, updated section 7.1.2 f) to reflect what action is actually satisfying the clause, updated the Raw Material Control Instruction and addressed Customer Supplied gaging in section 7.6.
O	6/9/16	**Updated the Supplier Approval and Monitoring Instruction process in Section 7.4 to include types of companies that MUST be present on the Approved Supplier List. 2016 Recertification Audit**
P	10/7/16	**Updated section 7.4.2 with requirement for supplier-related customer requirements to be flowed down on all part specific purchase orders. Updated the Purchasing Process as well. Issue 3856.**
Q	3/6/17	**Added 6.2.2 to the Standard Sections to be Audited for all five PEARS. Added the Revision of Documents process to section 4.2.3 and ensured there was a step for recalling obsolete documents (Issue #4069). Removed the requirement of a poor performance CAR due to the number of CARs issued to a Supplier. Updated verbiage in section 8.5.2 from Corrective Action Request to Corrective Action Report (QAF-10).**
R	4/1/18	**Updated manual format and context to conform to AS9100 Rev. D.**
S	2/5/20	**Added "Process" to each process and removed "PEAR#x" from Process Sequence and Interaction Flow Chart. Removed "PEAR#x" from each process page (9-13) and added "Process" to each process. Changed "Product" to "Process" in Management Process. Removed 6.1 in Audit section of Contract Administration Process. Removed 8.2.3 and added 8.1 to Audit section in Manufacturing Process. Added 10.1, 10.2 and 10.3 to Audit Section in Purchasing Process. Removed 7.1.3 and 8.5.5 from Auditing section in Shipping and Receiving Process. Changed "Sales Engineer" to "responsible individual" in Section 8.2.4.**
T	7/17/20	Updated section 10.2 to say "All customer returns will have corrective action assigned." for Issue 5902. Updated section 10.3 to say "Once an improvement action has been deemed complete, it will be audited or verified for effectiveness." for Issue 5903. Updated section 7.5.3.2 d) to say "Retention periods for documented information not included in the MDL will be 10 years." for Issue 5904.
U	2/25/21	Included frequency of MRM in section 9.3.
V	5/11/22	Updated section 8.6 to address First Piece or Workmanship Parts at the bench.
W	10/27/23	Removed the reference to ISO13485 and ISO9001 at the top of page 7. Removed the verbiage "of all 3 Standards" from the box on page 7. Removed the verbiage "Process, Preservation, Identification /Traceability, Packaging" from the Shipping & Receiving Box. Re-sized the "No" box in the Manufacturing Process flow chart on page 13. Added the verbiage "QAF-140 New/Revised Document Request" just before the word "approval" in Section 5.3.e on page 17. Removed the reference to ISO13485 and ISO9001 at the top of page 30. Removed the verbiage "of all 3 Standards" from the box on page 30. Removed the % sign that follows the 1.0 and 10.0 AQL levels in the Sampling Instruction box on page 37. Removed the % sign that follows the 1.0 AQL level in Section 8.5.1.k on page 38. Updated the verbiage in the Production Process Verification Process (First Article Inspection) box from "part drawing" to "part print" on page 40. Added if corrections are made, the original data must remain legible with the correction initialed and dated to 7.5.3.2, paragraph B, page 23. Revise 8.5.1.3 (page 39) to add first article inspection planning as per AS9102 rev C requirement for a documented plan to process FAI (4.1 of AS9102C) as well as adding a documented process to evaluate changes that invalidate or are not represented in the previous FAI (4.5 Note of AS9102C).

4 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and its Context

Witco determines the external and internal issues relevant to its purpose and strategic direction and that affect its ability to achieve the intended results of the QMS during Management Review Meetings (MRM) and referencing Witco's Corporate Strategy document.

Witco monitors and reviews information about these issues periodically and discusses them during MRMs.

4.2 Understanding the Needs and Expectations of Interested Parties

Witco determines, monitors and reviews interested parties relevant to the QMS and their requirements during MRMs. All interested parties and their requirements are taken into consideration when making decisions concerning the QMS.

4.3 Determining the Scope of the Quality Management System

Witco has established the following as its scope:

"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.

Witco has determined the following requirements not applicable to its scope:

Clause	Topic	Justification Statement
8.3	Design and Development of Products and Services	Product design is not required by our customers and not performing this process does not adversely affect product or service compliance or customer satisfaction.

4.4 Quality Management System and Its Processes

4.4.1
This 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 using the quality policy, quality objectives, audit results, corrective and preventive action and management review.

Witco has identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Sequence and Interaction Flow Chart below.

Witco has

a) determined the inputs required and outputs expected for each of these processes in the PEAR Section,
b) determined the sequence and interaction of these processes and documented them on the Process Sequence and Interaction Flow Chart,
c) determined and applied use of internal audits, organizational 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 MRMs and the Purchasing Process,
e) assigned responsibilities and authorities for these processes in the PEAR Section,

f) addressed the risks and opportunities determined in Section 6.1 Actions to Address Risks and Opportunities during MRMs and logged them in the Action and Issues Log when appropriate,
g) established a system to monitor, measure and analyze these processes utilizing the organizational objectives and KPIs,
h) established a system to improve these processes and the QMS through Section 10 Improvement and the Action Log.

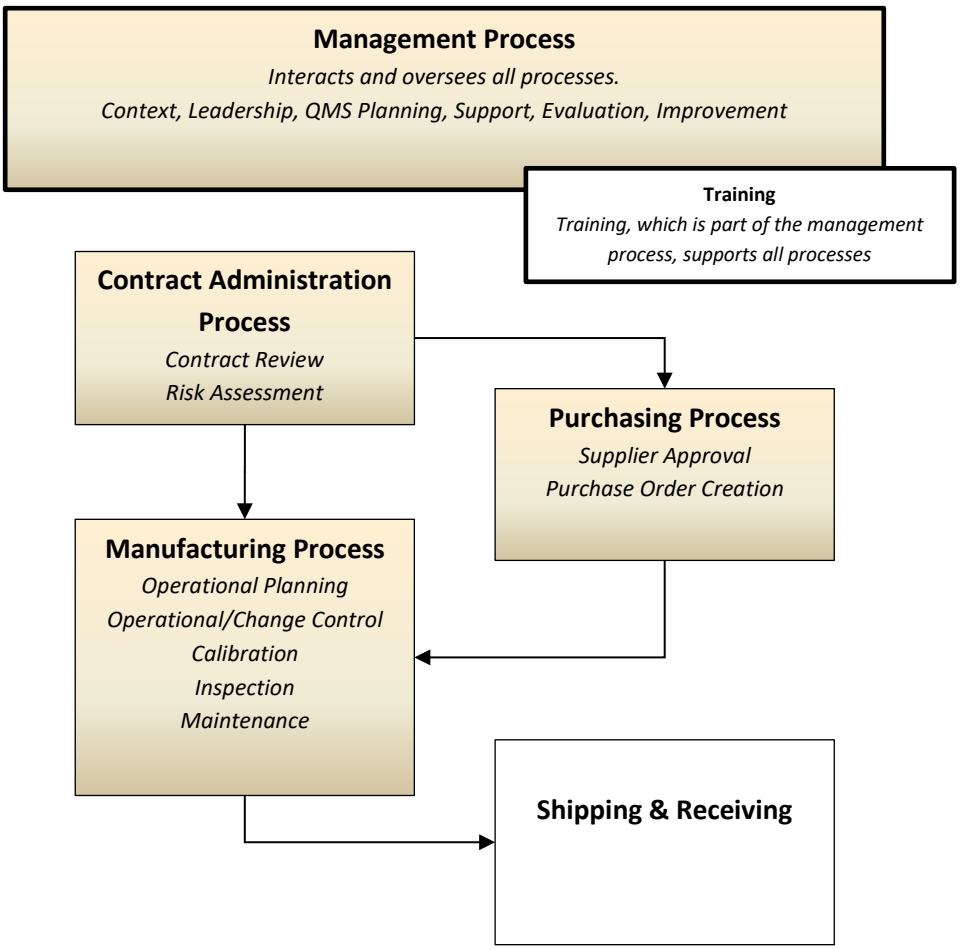
4.4.2
Witco has, to the extent necessary,

a) maintained documented information to support the operation of these Processes through procedures, work instructions and other relevant documents throughout this Quality Manual and the Master Document List (MDL);
b) retained documented information per the record retention information in the MDL to have confidence the processes are being carried out as planned.

Witco has established and maintained documented information that includes:

- a general description of interested parties as documented in Section 4.2 Understanding the Needs and Expectations of Interested Parties in the MRM Minutes;
- the scope of our QMS as documented in Section 4.3 Determining the Scope of the Quality Management System;
- a description of the processes needed for the QMS and their application throughout the organization documented in the PEAR Section;
- the sequence and interaction of these processes in the Process Sequence and Interaction Flow Chart;
- assignment of the responsibilities and authorities for these processes in the PEAR Section.

Process Sequence and Interaction Flow Chart



Management Process

Management Process

Process Owner: General Manager

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.

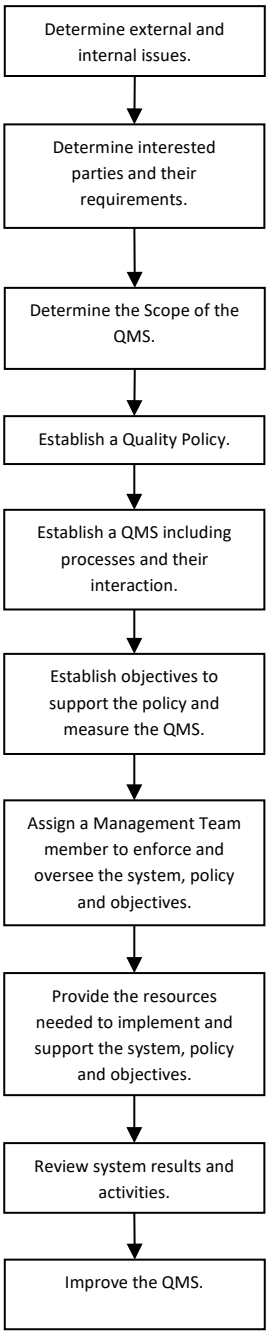
Inputs

- Organizational Context
- Requirements of Interested Parties
- Results of Audits
- Customer Feedback
- Organizational Objectives & Process KPIs
- Previous MRM Action/Minutes
- Changes that could affect the QMS
- Recommendations for Improvement
- Effectiveness of Training
- Issues Log

Outputs

- Corporate Strategy
- Internal Communication
- QMS Improvements
- Process Improvements
- Management Review Minutes
- Resource Needs

Standard Sections to be Audited:
4.1, 4.2, 4.3, 4.4, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.3, 6.1, 6.2, 6.3, 7.1.1, 7.1.2, 7.1.3, 7.1.4, 7.1.6, 7.2, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3, 9.1.1, 9.1.2, 9.1.3, 9.2, 9.3.1, 9.3.2, 9.3.3, 10.1, 10.2, 10.3



Contract Administration Process

Process Owner: Sales Manager

The contract administration process is responsible for the preparation of customer quotations, contract review and assessing risk.

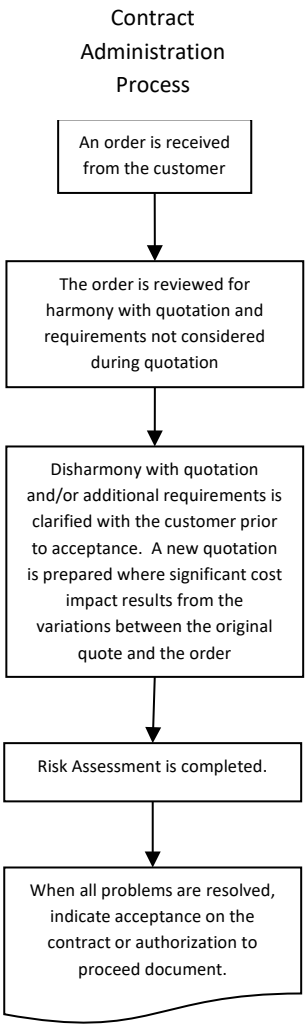
Inputs

- Customer Purchaser Order
- Customer Print
- Customer Requirements
- Witco's Estimate Audit

Outputs

- Sales Order
- Contract Review
- Risk Assessment
- Shop Paper
- Resource Needs
- Supplier Quotes

Standard Sections to be Audited:
7.1.1, 7.5.1, 7.5.2, 7.5.3, 8.1.1, 8.1.2, 8.1.3, 8.1.4, 8.2.1, 8.2.2, 8.2.3, 8.2.4, 8.5.2



Purchasing Process

Process Owner: Sales Manager

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

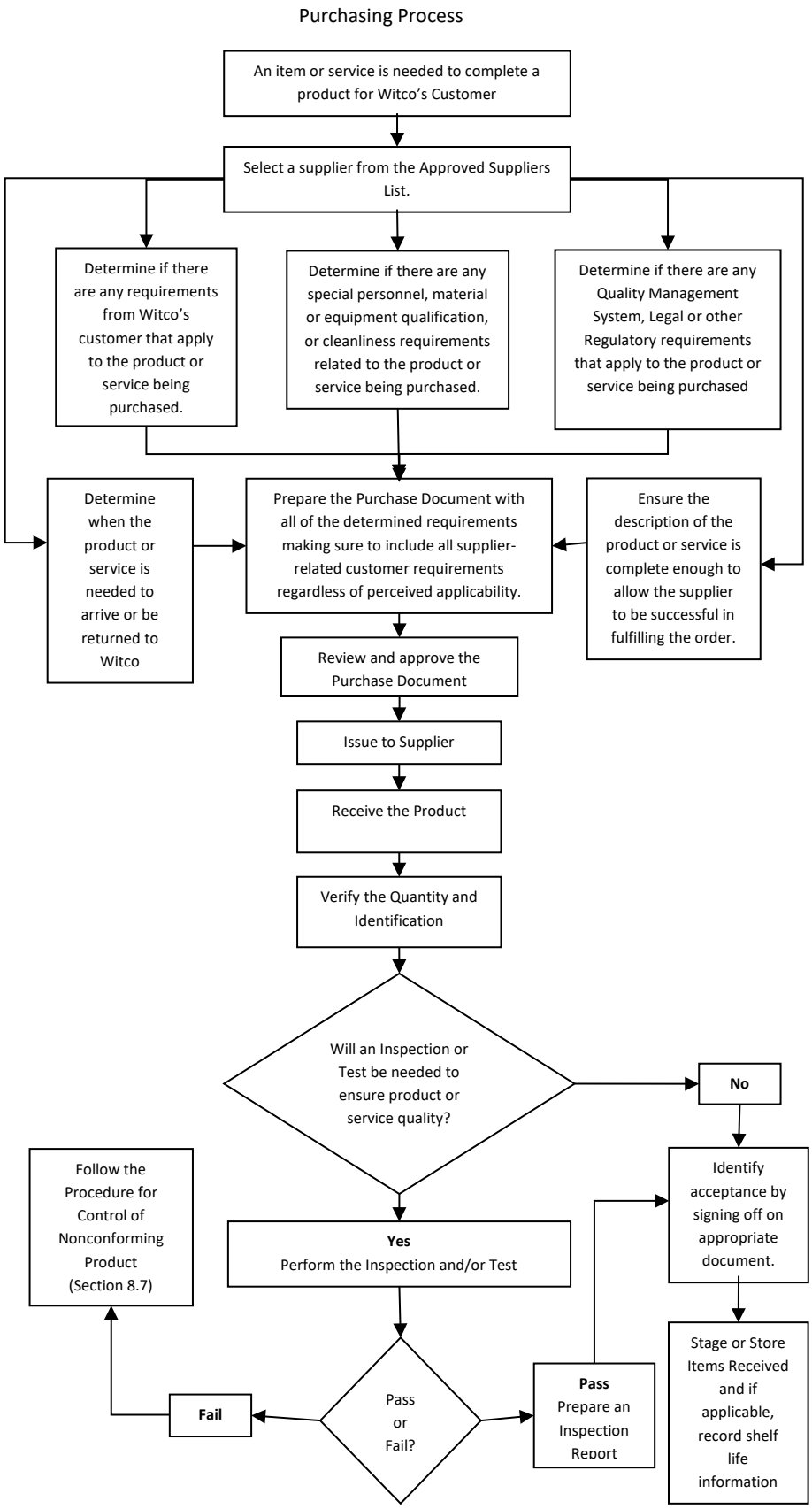
Inputs

- Approved Supplier List
- Risk Assessment
- Shop Paper
- Customer Specifications
- Supplier Quotes

Outputs

- Material
- Services
- Other Resource Needs
- Certifications

Standard Sections to be Audited: 7.1.1, 7.5.1, 7.5.2, 7.5.3, 8.1.4, 8.4.1, 8.4.2, 8.4.3, 8.5.1, 8.5.2, 8.5.3, 8.7, 10.1, 10.2, 10.3, Supplier CARs



Manufacturing Process

Process Owner: Plant Manager

The manufacturing process is responsible for operational planning, change control, operational control, calibration, inspection and maintaining resources.

Inputs

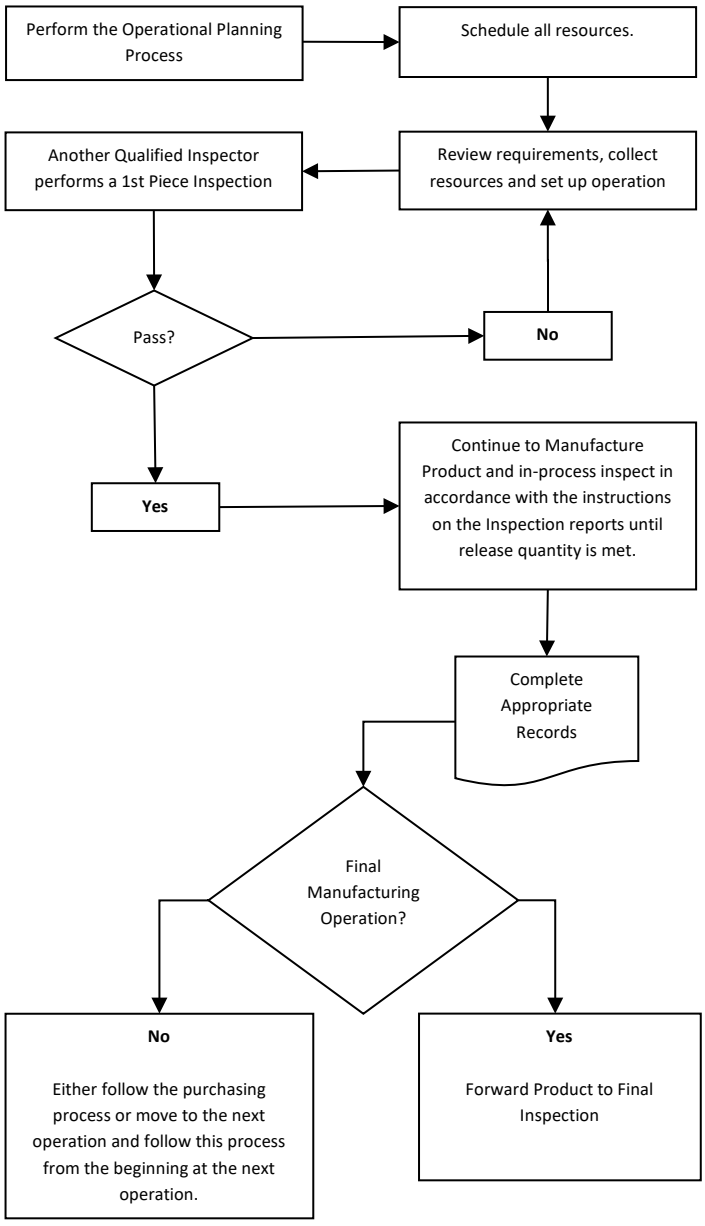
- Sales Order
- Contract Review
- Risk Assessment
- Shop Paper
- Material
- Services
- Other Resource Needs
- Preventive Maintenance Schedule

Outputs

- Shop Print
- Process Drawings
- Shop Paper
- Setup Sheets
- Tool Sheet
- Programs
- Suggested Gages
- Inspection Records
- Completed Parts
- Certifications
- Preventive Maintenance Records

Standard Sections to be Audited:
7.1.1, 7.1.3, 7.1.4, 7.1.5, 7.5.1, 7.5.2, 7.5.3, 8.1, 8.1.2, 8.1.3, 8.1.4, 8.2.1, 8.2.4, 8.5.1, 8.5.2, 8.5.3, 8.5.4, 8.5.5, 8.5.6, 8.6, 8.7, 10.2

Manufacturing Process



Shipping and Receiving Process

Process Owner: Quality Assurance Manager

The shipping and receiving process is responsible for preservation, identification, traceability and packaging of product for inventory or immediate shipment.

Inputs

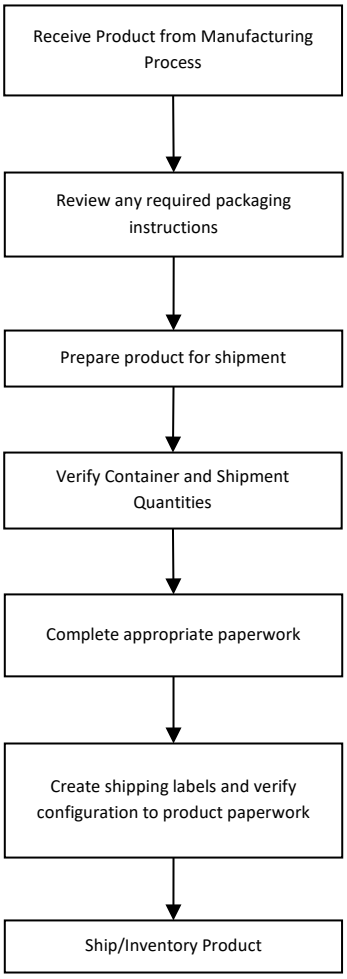
- Contract Review
- Sales Order
- Shop Paper
- Special Packaging Requirements
- Completed Parts
- Inspection Records
- Certifications

Outputs

- Shipment Documentation

Standard Sections to be Audited:
7.5.1, 7.5.2, 7.5.3, 8.1.4, 8.5.2, 8.5.3, 8.5.4, 8.6, 8.7

Shipping and Receiving Process



5 LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the QMS by:

a) taking accountability for the effectiveness of the QMS by making necessary improvements through MRM's, reviewing internal audits and analyzing KPI's.
b) ensuring the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization through MRM's;
c) ensuring the integration of the QMS requirements into the organizations business processes using Witco's Corporate Strategy;
d) promoting the use of the process approach and risk-based thinking through implementation of relevant processes, training and communication;
e) ensuring the resources needed for the QMS are available through Section 7 Support, Section 8.4 Control of Externally Provided Processes, Products and Services, MRM's and daily communication;
f) communicating the importance of the effective quality management and of conforming to the QMS requirements through training, internal auditing and daily communication;
g) ensuring the QMS achieves its intended results through review of KPI's and implementing improvement actions when they don't;
h) engaging, directing and supporting persons to contribute to the effectiveness of the QMS through training, internal auditing and daily communication;
i) promoting improvement through Section 10 Improvement, training, internal auditing and daily communication;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility through training, providing strategic direction and supplying necessary resources.

5.1.2 Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined and understood during the Contract Administration process and consistently met during all other processes;
b) the risks and opportunities that can affect conformity of products and the ability to enhance customer satisfaction are determined and addressed during the Risk Assessment process in Section 8.1.1 Operational Risk Management;

c) the focus on enhancing customer satisfaction is maintained through review of KPI's, Issues Log and daily communication and improvement actions taken when it isn't;
d) product conformity and on-time delivery performance are measured to give evidence of customer focus. Witco has assigned all KPIs a process effectiveness value which is consistent with the goals of Witco and are meant to maintain customer satisfaction. If process effectiveness values are not, or will not be, achieved, an issue will be entered into the Issues Log and corrective action assigned.

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.

5.2 Policy

5.2.1 Establishing the Quality Policy

Top management has established, implemented and maintains a quality policy that:

a) is appropriate to Witco's purpose and context of the organization and supports its strategic direct;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy applicable requirements;
d) includes a commitment to continually improve the effectiveness of the QMS.

5.2.2 Communicating the Quality Policy

The quality policy will:

a) be available and maintained in the Master Document List and numerous posting throughout the facility;
b) be communicated, understood and applied within the organization through training, internal auditing and daily communication;
c) be available to relevant interested parties through the Master Document List, internal postings and supplied upon request.

5.3 Organizational Roles, Responsibilities and Authorities

Top management shall ensure the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management has assigned a Management Representative who has the freedom and unrestricted access to top management to resolve QMS issues and the responsibility and authority for:

a) ensuring the QMS conforms to the requirements of this International Standard by utilizing internal audits;
b) ensuring the processes are delivering their intended outputs through internal audits and KPIs;
c) reporting on the performance of the QMS and opportunities for improvement by utilizing the Issues Log for preventive and corrective action and MRM;
d) ensuring promotion of customer focus throughout the organization;
e) ensuring the integrity of the QMS is maintained when changes are planned and implemented through QAF-140 New/Revised Document Request approval and internal audits.

6 PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1

When planning for the QMS during MRM, the organization shall consider the issues referred to in Section 4.1, the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance the QMS can achieve its intended results;
b) enhance desirable effects;
c) prevent or reduce undesired effects;
d) achieve improvement.

6.1.2

The organization shall plan:

a) actions to address these risks and opportunities that will be documented on the Action Log;
b) how to:
    a. integrate and implement the actions into the QMS processes (see 4.4)
    b. evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.2 Quality Objective and Planning to Achieve Them

6.2.1
Witco has established quality objectives at relevant functions, levels and processes needed for the QMS.

The quality objectives:

a) are consistent with the quality policy in Section 5.2.1 Establishing the Quality Policy;
b) are measured using the KPI's;
c) take in account applicable requirements including those required by this standard;
d) are relevant to conformity of products and services and to enhancement of customer satisfaction;
e) are recorded monthly and evaluated quarterly;
f) are communicated using the Issues Log and by posting throughout the plant;
g) are updated as appropriate through top management suggestion and strategic direction changes.

Witco maintains documented information on the quality objectives on the KPI Report and in the Issues Log.

6.2.2

When planning how to achieve its quality objectives, Witco will utilize the Action Log to determined:

a) the actions that will be taken;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

6.3 Planning of Changes

When Witco determines the need for changes to the QMS, the changes will be carried out in a planned manner utilizing the Action Log, Issues Log or the preventive/corrective action process.

Witco considers:

a) the purpose of the changes and their potential consequences;
b) the integrity of the QMS;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

7 SUPPORT

7.1 Resources

7.1.1 General

Witco has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS through MRM, the Contract Administration Process and the Operation Planning Process.

Witco has considered:

a) the capabilities of and constrains on existing internal resources;
b) what needs to be obtained from external providers.

7.1.2 People

Witco has determined the persons necessary for the effective implementation of its QMS and the operation and control of its processes through the Org Chart without Names and provided those persons.

7.1.3 Infrastructure

Witco determines, provides and maintains an infrastructure necessary for the operation of its processes and to achieve conformity of products through MRM's, Section 8.1 Operational Planning and Control and daily communication.

7.1.4 Environment for the Operation of Processes

Witco determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products through MRM's, Section 8.1.1 Operational Risk Management, internal audits and interested party suggestion.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Witco has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products to requirements.

Witco has ensured the resources provided:

a) are suitable for the specific type of monitoring and measurement activities to be undertaken by using the customer supplied print (Shop Print) and the Suggested Gages form. 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".
b) are maintained to ensure their continuing fitness for their purpose through Section 7.1.5.2 Measurement Traceability.

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

Witco retains the results of calibration and verification information as evidence of fitness for purpose.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by Witco to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated and/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 documented;
b) identified legibly and conspicuously, either on the equipment or equipment container, with a gage number so calibration status can be determined;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results by checking gaging during gage setup, 1st Piece Inspection, product audits and morning checks.

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

Witco maintains a register of the monitoring and measuring equipment, including employee owned gaging, and defines the process employed for their calibration/verification including details of equipment type, unique identification number, location, check method, frequency of checks and acceptance criteria. A register of customer supplied gaging is also maintained and the equipment is verified upon receiving but calibration of gaging is completed by the customer.

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.

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.).

7.1.6 Organizational Knowledge

Witco determines the knowledge necessary for the operation of its processes and to achieve conformity of products.

This knowledge is maintained in this Quality Manual, Issues Log, processes, procedures, work instructions, forms and training documents.

When addressing changing needs and trends, Witco will consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. This is done in MRM's, Section 8.1 Operational Planning and Control, top management suggestion and daily observances. Witco uses both internal and external sources.

7.2 Competence

Witco:

a) has determined the necessary competence of a person doing work under its control that affects the performance and effectiveness of the QMS and it's documented in Witco Shop;
b) ensures personnel performing work that affects the performance and effectiveness of the QMS will be competent on the basis of appropriate education, training or experience which will be documented in Witco Shop or their employee file;
c) continuously provides training through the QMS Manual and other documents to ensure all employees achieve the necessary level of competency and evaluates the effectiveness of employee training through review of the Employee Competency metric and employee reviews;
d) retains training documents in Witco Shop as evidence of employees competence.

Document Training Tracking
The Document Training Tracking located in Witco Shop serves as a master record of employee training by indicating the job descriptions for which each employee is trained and the level of training. Levels include:

- Acknowledged – Currently in training to perform the position.

- Fully Competent – Fully competent to perform the position.
- Able to Train Others – Fully competent to train and perform the position.
- Able to Substitute – To be trained on all aspects of the position when it's been determined they will be substituting. This normally means the employee has previously held this position.

7.3 Awareness

Witco, through new hire orientations, facility postings, internal communication and training, ensures persons doing work under their control, are aware of:

a) the quality policy;
b) relevant quality objectives by posting them throughout the facility;
c) their contribution to the effectiveness of the QMS including the benefits of improved performance;
d) the implications of not conforming with the QMS requirements;
e) relevant QMS documented information and changes thereto;
f) their contribution to product conformity;
g) their contribution to product safety;
h) the importance of ethical behavior.

7.4 Communication

Witco has determined the internal and external communications relevant to the QMS through the processes in this Quality Manual, procedures, forms, other documents and customer, supplier and regulatory requirements.

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

- The Issues Log
- Internal Audit Reports
- KPI's

7.5 Documented Information

7.5.1 General

Witco's QMS includes:

a) documented information required by the International Standard;
b) documented information necessary for the effectiveness of the QMS.

7.5.2 Creating and Updating

When creating and updating documented information, Witco will ensure appropriate:

a) identification and description by using a descriptive title and a visually apparent revision status;
b) format (including customer required formats) and media (paper or electronic);
c) review and approval for suitability and adequacy. As a minimum, all Quality Management System documents created by Witco shall be approved by either the "approved by" individual documented on the Master Document List or the creator of the document. The approval can be by signature, initial or electronic application. The approval indicates that this individual has reviewed the document for suitability and adequacy and authorizes its implementation.

7.5.3 Control of Documented Information

7.5.3.1

Documented information required by the QMS and this International Standard is controlled to ensure:

a) 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, at its point of use or designated software. 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.
b) 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. Electronic records will be stored in an environment that receives regular back up to prevent loss.

7.5.3.2

For the control of documented information, Witco will address the following activities as applicable:

a) All documented information created by Witco will either be present in the Master Documents List, be controlled through Section 8.1 Operational Planning and Control or be from designated software. Only the most recent version of documented information will be available. Retrieval information is also located in the Master Documents List. Documented information is available for review by customers and regulatory authorities in accordance with contract or regulatory requirements at our facility;
b) Documented information shall remain legible, readily identifiable, and retrievable (if corrections are made, the original data must remain legible with the correction initialed and dated). It will be stored in a manner that preserves its legibility. Documented information will be stored in a manner that is indexed by a common theme (customer, part number, job number, date, etc.);
c) The QAF-140, New/Revised Document Request form, will specify changes made to all Witco created documents and Section 8.1 Operational Planning and Control will control the changes of product specific documents.
d) The Management Representative, the individual responsible for approving the document or customer or regulatory requirements will determine retention duration for documented information. When required, these same parties will determine the proper disposal method of

documented information exceeding the retention requirements or at the time it is determined that it is no longer necessary to retain the information. Retention periods for documented information not included in the MDL will be 10 years.

e) If necessary, for legal purposes, compliance with customer and/or regulatory agency requirements and Witco's business practices, 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.

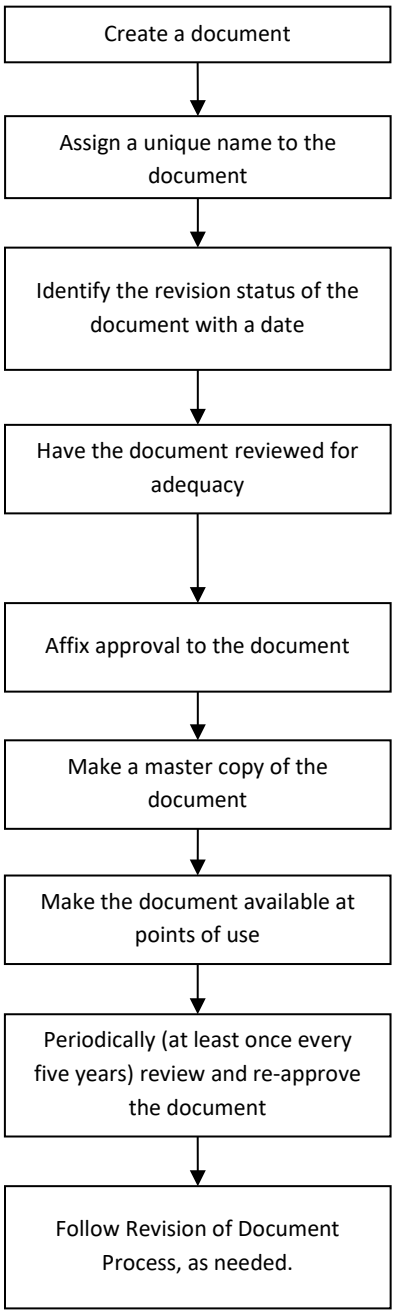
Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS is identified as appropriate and controlled using Section 8.1 Operational Planning and Control or being entered into the Master Document List appropriately. Export documentation will be prepared in accordance with statutory and regulatory requirements.

Documented information retained as evidence of conformity will be protected from unintended alterations.

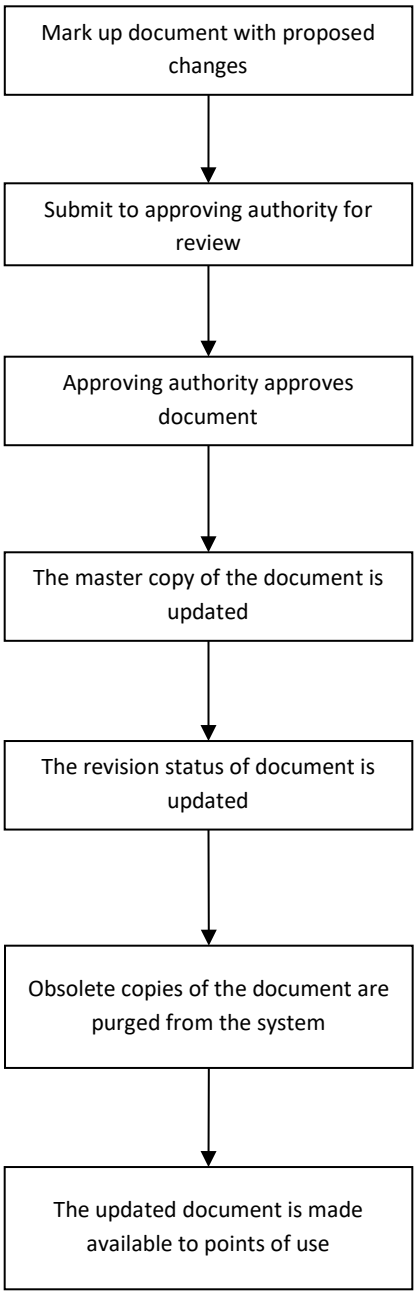
Electronic data and records are backed up daily to safe guard the organization from loss. Access to data is managed using firewall security at the company level, passwords at the system level and security settings at the individual user level.

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

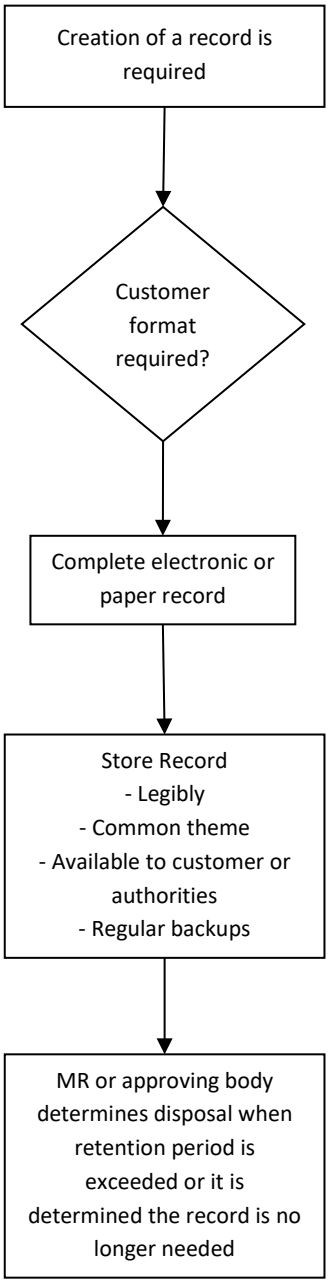
Control of Documents Process



Revision of Documents Process



Control of Records Process



8 OPERATION

8.1 Operational Planning and Control

Witco plans, implements and controls the processes needed to meet the requirements for the provision of products and to implement the actions determined in Section 6 Planning, by:

a) determining the requirements for the products including, but not limited to, safety, availability, producibility and inspectability;
b) establishing criteria for:
    a. product specific processes, documents and resources through the Shop Paper, Shop Print and Process Drawings;
    b. verification, validation, monitoring, measurement, inspection/test activities and criteria for product acceptance through Inspection Reports and Suggested Gages forms;
c) determining the resources needed to achieve conformity to product requirements and to meet on-time delivery of products through the Contract Administration Process, the Operational Planning Process and the Risk Assessment;
d) implementing control of the processes in accordance with the criteria using Section 8.5.1 Control of Production and Service Provision and Section 8.5.6 Control of Changes;
e) determining, maintaining and retaining the Shop Print, Shop Paper, Process Drawings, Inspection Reports, etc. to the extent necessary:
    a. to have confidence that the processes have been carried out as planned;
    b. to demonstrate the conformity of products to their requirements;
f) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified by the customer, using the Operational Planning Process and the Sampling Instruction in Section 8.5.1 Control of Production and Service Provision;
g) engaging representatives of affected organizational functions for operational planning and control using the job release function in Witco Shop and Kick Off Meetings when applicable;
h) determining the process and resources to support the use and maintenance of the products through the Operational Planning Process;
i) determining the products to be obtained from external providers during the Contract Administration and Purchasing Process;
j) establishing the controls needed to prevent the delivery of nonconforming products to the customer through the Control of Nonconforming Product Process and inspections.

Witco plans and manages product in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints using the Risk Assessment and Operational Planning Process.

The output of this planning is the Shop Paper, Shop Print, Process Drawings, Tool Sheets, resource expectations, Inspection Reports, Suggested Gage forms, special packaging requirements, etc. Planned changes are controlled using the Operation Planning Process and the consequences of unintended changes are reviewed using the Control of Nonconforming Product Process or Corrective Action Process. Actions derive from these processes to mitigate risk as necessary.

Witco ensures outsourced processes are controlled per Section 8.4 Control of Externally Provided Processes, Products and Services.

Work transferred from Witco to external provider or external provider to external provider, will be controlled by the Purchasing Process. Once work transferred is complete and returned to Witco, it will be inspected per Section 8.4.2 Type and Extent of Control to verify conformance to specifications.

Operational Planning 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, gaging 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. Determine special packaging requirements. 11. Identify any other special requirements such as customer designated special characteristics. 12. Create the Shop Paper and schedule to meet delivery requirements. (Process Output)

8.1.1 Operational Risk Management

Witco plans, implements and controls both the Risk Assessment process and the Issues Log in Witco Shop for managing operational risks to the achievement of applicable requirements, including:

a) assignment of responsibilities,
b) the definition of risk assessment 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 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 order.

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 Manufacturing Process and Purchasing Process for incorporation into appropriate scheduling and manufacturing instructions.

8.1.2 Configuration Management

Witco is not the design authority for the products they produce. However, Witco plans, implements and controls a configuration management process appropriately to ensure the identification and control of physical and functional attributes throughout the products lifecycle. The configuration management process:

a) controls product identity and traceability to requirements including revisions through a Witco job number. Identification of part number, part revision levels, operation process and operation process revision levels are present on all documents, records and labels (including finished goods) throughout processing.
b) ensures the documented information is consistent with the actual attributes of the product. This includes verification of engineering revision levels during the Contract Administration Process, auditing of the part and process engineering revision levels at the Operational Planning Process, during scheduled inspections, at packaging and during internal audits where revision levels of finished goods inventory will also be verified.

8.1.3 Product Safety

Witco plans, implements and controls the Risk Assessment and Operational Planning Process to assure product safety during the entire product life cycle. Any and all safety requirements will be communicated through the Issues Log, on the Shop Paper, prints or drawings and training offered as appropriate.

8.1.4 Prevention of Counterfeit Parts

While the risk of Witco encountering counterfeit parts is low, we have planned, implemented and controlled a process for the prevention of their use and inclusion in product delivered to the customer.

- Relevant personnel have been trained counterfeit parts exist and they should be on the lookout for false identification of marking or labeling, grade, serial number, date code, documentation or performance characteristics;

- Controls for externally provided product through Section 8.4 Control of Externally Provided Processes, Products and Services;
- Requirements for assuring traceability of parts and components to their original or authorized manufactures through Section 8.4 Control of Externally Provided Processes, Products and Services;
- External monitoring of counterfeit parts if needed;
- Quarantine and report of suspect or detected counterfeit parts using Section 8.7 Control of Nonconforming Outputs.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

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;
c) customer feedback, including customer complaints which are entered into the Issues Log for management review.
d) handling or controlling customer property as per Section 8.5.3 Property Belonging to Customer or External Providers;
e) establishing specific requirements for contingency actions when needed.

8.2.2 Determining the Requirements for Products and Services

Witco determines customer requirements during the Contract Administration Process and will:

a) define customer, statutory and regulatory and Witco necessary requirements, including delivery and post-delivery activities;
b) meet the claims for products offered;
c) determine special requirements, including critical items and key characteristics, of the product;
d) identify operational risks during the Risk Assessment process.

8.2.3 Review of the Requirements for Products and Services

Witco ensures it has the ability to meet customer requirements before acceptance of an order during the Contract Administration Process. The review will include:

a) customer requirements, including delivery and post-delivery activities;
b) requirements not stated by the customer but necessary for intended use, when known;

c) any requirements specified necessary by Witco;
d) statutory or regulatory requirements applicable to the product, and
e) contract or order requirements differing from those previously expressed.

The review is normally conducted by the Sales Engineer but they will coordinate with other departments as needed.

If upon review Witco determines some customer requirements cannot be met, a mutually acceptable requirement will be negotiated. Reference Section 8.1.1 Operational Risk Management.

When product requirements differ from those previously defined, the Sales Engineer will resolve with the customer.

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.

8.2.3.2 Witco will retain the customer purchase order, job routing and/or the Risk Assessment which serve as documented evidence of:

a) the results of the review;
b) any new requirements for the product.

8.2.4 Changes to Requirements for Products and Services

When product requirements change, the responsible individual will update the relevant documents and forward these changes to planning.

8.3 Design and Development of Products and Services

Exclusions from AS9100 or ISO9001 and Justification for Exclusion:

Clause	Topic	Justification Statement
8.3	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.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

Witco ensures externally provided processes, products and services conform to requirements.

Witco is responsible for the conformity of all externally provided processes, products, and services, including those from sources determined by the customer.

Witco will use customer designated or approved external providers when required.

Witco identifies and manages the risks associated with the external provision of processes, products, and services as well as the selection and use of external providers using the Supplier Approval and Monitoring Instruction and the Supplier Evaluation Process to select and evaluate external providers.

Witco requires external providers to apply appropriate controls to their direct and sub-tier external providers to ensure customer requirements are met by flowing down necessary requirements through the Terms & Conditions and our purchase order.

Witco uses the Section 8.4.2 Type and Extent of Control to determine the extent of control to be applied to externally provided processes, products, and services when:

a) products and services from external providers are intended for incorporation into Witco's products and services;
b) products and services are provided directly to the customer by external providers on Witco's behalf;
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

Witco evaluates, selects, monitors and re-evaluates external providers based on the Supplier Approval and Monitoring Instruction and the Supplier Evaluation Process below. Records of the results of these evaluations and actions taken are retained.

8.4.1.1 Witco:

a) 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 external providers approval status according to the Supplier Approval and Monitoring Instruction below;
b) maintains the Approved Supplier List in Witco Shop that includes the scope of the supplier and its approval status;
c) reviews supplier performance using KPIs;
d) will create a Supplier NCM in Witco Shop and may issue corrective actions to external providers who fail to meet performance requirements. Continual failure will make the external provider subject to being placed on "Inactive" status and a search for a replacement external provider

will begin. External providers that refuse to respond to a corrective action request are subject for "Inactive" status and eventual replacement;

e) defines the requirements for controlling documented information created and/or retained by external providers as readily available to Witco Inc. for a period of ten years after component completion and is communicated by the Terms & Conditions.

Supplier Approval and Monitoring Instruction

This process is only performed for suppliers whose product or service adds value to Witco's QMS or the product Witco is supplying to its customer(s). Types of suppliers can include:

- Raw Material
- Special Tools & Gages
- Calibration & Testing Services
- Outsourced Parts Services
- Tooling & Gaging Services
- Manufacturing & Quality Equipment
- Part Components
- Quality Consulting Services
- Manufacturing & Quality Equipment Repair & Servicing

Suppliers **must** complete the Supplier Profile. Suppliers will also be asked to complete the Non-Disclosure Agreement, ITAR Compliance Letter and the Terms & Conditions Acknowledgement. The completion of these three documents is not required but can play a part in receiving approved status. The Sales Manager or a Management Representative must determine a risk level and approve a supplier prior to the issuance of a purchase order. High risk suppliers will be subjected to a critical receiving inspection. Emergency purchases may delay this process.

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 Sales Manager or 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.

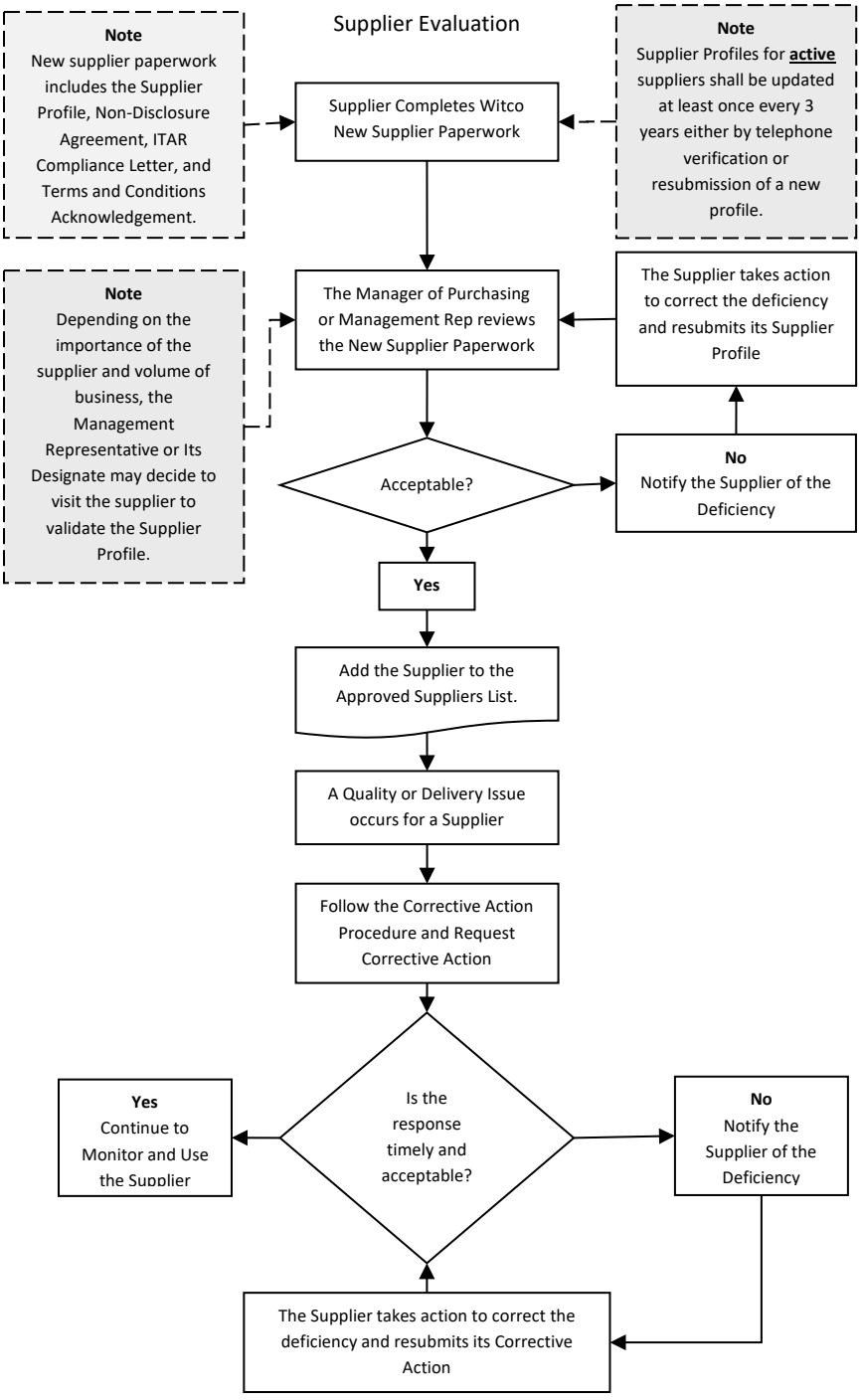
If Witco is required to choose from a list of suppliers prepared by our customer or a supplier required by our customer and the supplier has not been approved by Witco by this process, we will use those suppliers for that customer only.

Suppliers are evaluated continually and may be placed on "Inactive" status at any time at the discretion of the Sales Manager or Management Representative. Non-conformances, including late deliveries, are documented on a corrective action request at the discretion of a Management Representative. Suppliers may also receive corrective action request for poor performance. Inadequate responses or failure to respond may result in being placed on "Inactive" status.

The Sales Manager and the Management Representative have the ability to disapprove or inactivate a supplier at any time and for any reason.

Low Risk – Minimal risk supplier and no additional actions required.
Medium Risk – Some risk dealing with supplier and operational planning may incorporate additional actions to mitigate.
High Risk – Excessive risk dealing with supplier and operational planning will incorporate additional actions to mitigate.
Approved/Active – Supplier can be used without conditions.
Conditional – Supplier can be used within a set of circumstances.
Disapproved/Inactive – Supplier can't be used until approved/active.

Supplier Evaluation Process



8.4.2 Type and Extent of Control

Witco ensures externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products to our customers.

Witco:

a) ensures externally provided processes remain within the control of its QMS through inspection and KPIs;
b) defines the controls it intends to apply on an external provider and the resulting output through the purchase order, prints, drawings, Terms & Conditions and other relevant documentation;
c) takes into consideration:
    a. the potential impact of externally provided processes, products and services on the ability to meet customer, statutory and regulatory requirements during the Contract Administration and Operational Planning processes;
    b. the effectiveness of the controls applied by the external provider using inspection, certification and KPIs;
    c. the results of periodic review of external provider performance through KPI's;
d) conducts receiving inspections or obtains objective evidence from the supplier (certification of conformity, test records, etc.) when product is received to ensure externally provided processes, products and services meet requirements.

Verification activities of externally provided processes, products and services will be performed according to the risks identified during the Contract Administration process, Risk Assessment and Operational Planning Process. Inspection or periodic testing will be implemented if there is a high risk of nonconformity including counterfeit parts.

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.

When Witco delegates verification activities to the supplier, the scope and requirements for delegation will be present on Prints, Drawings and purchase orders. Copies of these PO's will be kept in a folder on the Buyer's desk as a register of these delegations. These activities will be periodically monitored.

When a test report is required and received with the product, 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 a customer or other organization identifies material as a significant risk, Witco will have the material tested by a 3rd party to validate the accuracy of the test reports.

8.4.3 Information for External Providers

Witco ensures the adequacy of requirements during the Operational Planning Process prior to communicating with the external provider. Additionally, purchasing documents are reviewed, initialed and dated for adequacy before they are communicated to the supplier.

Witco communicates its requirements for:

a) the processes, products and services to be provided including technical data which are located on the purchase order, print, drawing or other document;
b) the approval of:
    a. products and services which are located on the purchase order, print or drawing;
    b. methods, processes and equipment which are located on the purchase order, print or drawing;
    c. the release of products and services which is located on the purchase order, print or drawing;
c) competence, including any required qualification of personnel which is noted on the purchase order;
d) the external providers' interaction with the organization which is noted on the purchase order or the Terms & Conditions;
e) control and monitoring of the external providers' performance to be applied by the organization through product requirements stated on the purchase order, print, drawing and the Terms & Conditions;
f) verifications or validation activities that Witco or her customer intends to perform at the external providers' premises which is noted on the purchase order and in the Terms & Conditions;
g) design and development control which will be located on the purchase order if applicable;
h) special requirements, critical items and key characteristics which are communicated on the purchase order, prints or drawings;
i) test, inspection and verification will be noted on the purchase order or a separate document attached to the purchase order;
j) the use of statistical techniques for product acceptance and related instructions for acceptance which are noted on the purchase order;
k) the need to:
    - implement a QMS which is noted on the purchase order;
    - use customer-designated or approved external providers which is noted on the purchase order;
    - notify the organization of nonconforming processes, products or services and obtain approval for their disposition which is communicated through the purchase order or the Terms & Conditions;

- prevent the use of counterfeit parts which is communicated through the Terms & Conditions;
- notify Witco of changes to processes, products or services including changes of external providers or location of manufacture and obtain Witco's approval which is communicated through the purchase order or the Terms & Conditions;
- flow down to external providers applicable requirements including customer requirements which are located on the purchase order or the Terms & Conditions;
- provide 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;
- retain documented information including retention periods and disposition requirements which are present on the Supplier Profile or the Terms & Conditions;

l) 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 documented information which is stated in the Terms & Conditions and referenced on all purchase orders ;

m) ensuring the persons are aware of:
   a. their contribution to product or service conformity by providing a purchase order, prints and drawings;
   b. communicating product safety information on the purchase order, prints or drawings so they're aware of their contribution;
   c. the importance of ethical behavior through the Terms & Conditions.

All supplier-related customer requirements will be flowed down on all part specific purchase orders created, regardless of perceived applicability. (Issue #3856)

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Witco uses a Job Packet to plan and implement production and service provision under controlled conditions.

Controlled conditions include:

a) availability of documented information that defines:
   a. the characteristics of the product to be produced, services to be provided or the activities to be performed which are found on the prints, drawings and Shop Paper;
   b. the results to be achieved which are found on the prints, drawings and inspection reports;

b) the availability and use of suitable monitoring and measuring resources which are found on the Suggested Gages form;

c) the implementation of monitoring and measurement activities at appropriate stages to verify criteria for control of processes or outputs and acceptance criteria for products and services have been met;
    1. ensuring documented information for product acceptance includes:
        - prints and/or drawings that determine acceptance and rejection criteria;
        - training from Section 8.6 Release of Products and Services and in process inspection frequency on inspection reports;
        - inspection reports as records of measurement results;
        - the Suggested Gages form that specifies required measurement instruments and any relevant instructions for their use;
    2. ensuring that when sampling is used as a means of product acceptance, the Sampling Instruction will be used.

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 MIWI-40 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. 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 8.1.1 Operational Risk Management and a High Risk issue is created in the Issues Log. Resolution must be applied to the issue. Customer requirements take precedent over Witco's sample designations.

d) Shop Paper, setup sheets, programs or inspection reports which spell out suitable infrastructure and environment,
e) training records and experience to appoint competent person to activities;
f) special processes per Section 8.5.1.2 Validation and Control of Special Processes;
g) the Risk Assessment, Issues Log, Kick Off Meetings and Continual Improvement Process to allow for implementation of actions to prevent human error;
h) the Shop Paper and sales order for implementation of release, delivery and post-delivery activities;

i) the Shop Paper, prints, drawings and First Piece sample (if applicable) which define any criteria for workmanship;
j) the Shop Paper, Material Hold Tag, Parts Sign-Out Form, Outsourced Parts Sign-Out form, etc. which allows for accountability of all product during production. Shipping accounts for all parts before closing a job/order;
k) critical items including 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;
l) Suggested Gages form which communicates the methods to measure variable data;
m) inspection/verification points are learned through training, determined during the Operational Planning Process and inspection reports created appropriately when verification of conformance cannot be performed at later stages of realization;
n) 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;
o) the HRWI-360 Foreign Object Debris Prevention Program for the prevention, detection and removal of foreign objects;
p) the Shop Paper or setup sheets will instruct individuals appropriately so utilities and supplies can be monitored and controlled;
q) the Shop Paper and/or Witco Shop will be noted appropriately if product s are released for production pending completion of all measuring and monitoring activities to allow for recall and replacement if later it is determined that product doesn't meet requirements.

8.5.1.1 Control of Equipment, Tools and Software

Equipment, tools and software programs are validated prior to use during first piece inspection and maintained throughout production with in-process inspections and audits.

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. Documented information is 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 7.5 Documented Information. The identification of these programs shall also reference the engineering change status of the product for which it was created.

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, Witco has established arrangements in Section 8.4 Control of Externally Provided Processes, Products and Services for these processes including, as applicable:

a) defined criteria for review and approval of the processes;
b) determination of conditions to maintain the approval;
c) approval of facilities and equipment;
d) qualification of persons;
e) use of specific methods and procedures for implementing and monitoring the processes;
f) requirements for documented information to be retained.

8.5.1.3 AS9102 Rev C First article inspection planning

Witco's first article inspection planning is accomplished in conjunction with planning for the first production run, following the steps outlined in Witco's QMS manual. Additional first article inspection planning includes.

1. Determining the required supporting documentation to be included in the FAIR based upon customer requirements as well as AS9102. This may include but is not limited to certifications, inspection reports, test reports, ballooned prints, etc.
2. Planning for customer reviews of the FAI process if required, communicated through the issue log and or kick off meetings.
3. Changes to the product realization processes or engineering / design requirements that invalidate or are not represented in the previous FAI are evaluated during the contract administration process. If a FAI is required, it is communicated on the shop paper. The evaluation shall be performed when any of the following occur.
   a. A change in Engineering definition affecting design characteristics.
   b. A change in manufacturing sources, processes, inspection methods, tooling, materials, or location of manufacture.
   c. Programs used to perform computerized operations should be reviewed for impact and may require a full or partial FAI.
   d. A natural or man-made event which can adversely affect the manufacturing process.
   e. An implementation of corrective action required to complete a previous FAI.
   f. A lapse in production for two years for any characteristics that may be impacted. This lapse is from the completion of the last production operation to the actual restart of production.

4. FA Planning complete ready for data noted in Witco Shop verifies planning activities are complete.

8.5.1.4

Production process verification shall be performed at the beginning of each operation (First Piece Inspection) and on a completed part from the first production run as required by the customer (First Article). 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 print). 3. Prepare an inspection report with numbers that correspond to those identified on the print. 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. Provide documents to the customer as necessary and retain records appropriately.

8.5.2 Identification and Traceability

Witco uses the Shop Paper, Box Tickets, Approved First Piece, Material Hold, Material Inventory Tags, etc. for identification throughout operations. 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, Non-Conforming Material Report and/or red layout dye 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 them. 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. Documented information comes in many forms but is usually located in the Part Folder, JobBoss Windows, JobBoss DOS or Witco Shop.

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 an appropriate identification number and may not be mixed in the same container.

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

8.5.3 Property Belonging to Customers or External Providers

Witco will exercise care when customer or external provider property is being used or in our care.

Customer or external provider property will be identified (SRF-80 Internal Receiver – Customer, Material Inventory Tag, Shop Paper, etc.), verified for damage and adequacy upon receipt, and protected and safeguarded appropriately for the type of property and its application.

Issues with customer or external provider supplied items shall be reported to the customer for disposition and documented according to Section 7.5 Documented Information.

8.5.4 Preservation

Witco will preserve outputs during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation includes, when applicable, identification of the product 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.

8.5.5 Post-Delivery Activities

Witco will meet post-delivery support requirements as associated with the product.

When determining the extent of post-delivery activities that are required, Witco will consider:

a) statutory and regulatory requirements as stated in the customer contract documents;
b) the potential undesired consequences associated with its products, if known;
c) the nature, use and intended lifetime of its products, if known;
d) customer requirements as stated in the customer contract documents;
e) customer feedback as captured in the Issues Log;
f) the collection and analysis of in-service data as provided by the customer,
g) control, updating and provision of technical documentation relating to product use, maintenance, repair and overhaul provided by the customer;
h) controls required for work undertaken external to the organization which are determined by the Management Representative, Sales Manager and/or the Engineering Manager and based on the nature of the work to be completed;
i) product/customer support as requested by the customer.

When problems are detected after delivery, Witco will take actions, including investigation and reporting, utilizing Section 10.2 Nonconformity and Corrective Action.

8.5.6 Control of Changes

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.

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

Witco retains documented information describing the results of the review of changes on inspection reports, the person authorizing the change through documented initials or employee number and actions arising from the review utilizing the proper location for the type of action implemented.

8.6 Release of Products and Services

Witco has implemented planned arrangements, at appropriate stages, to verify product requirements have been met.

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". In certain rare circumstances, it may be impossible to keep a First Piece or Workmanship Part present at the bench. In these cases, the QAF-004 tag shall be present and noted appropriately. (Reference Issue 6225)
- 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 frequency on the inspection report.

Receiving Inspections

- See Section 8.4.2 Type and Extent of Control.

Final Inspections

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

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 8.1 Operational Planning and Control.

Where product is released for production use pending completion of all required measurement and monitoring activities, it will be identified and recorded on the Shop Paper and 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.

Witco retains documented information on the release of products. It includes:

a) inspection reports (created from Shop Print and/or Process Drawings) that determine acceptance criteria;
b) inspection reports, Shop Paper sign off and Witco Shop inspection entries that are traceable to the person authorizing the release.

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

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

8.7 Control of Nonconforming Outputs

8.7.1
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.

Witco will take appropriate action based on the nature of the nonconformity and its effect on product conformity. This will also apply to nonconformances detected after delivery.

Witco's Control of Nonconforming Product process is maintained as documented information and includes:

- defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- taking actions necessary to contain the effect of the nonconformity on other processes, products or services;
- timely reporting of nonconformities affecting delivered products to the customer and to relevant interested parties;
- defining corrective actions for nonconforming products detected after delivery, as appropriate to their impacts.

Control of Nonconforming Product Process

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 holding the job descriptions have the experience and skills necessary to make these decisions.

Disposition Categories

Scrap – Product deemed scrap must be permanently and conspicuously identified, stored in a separate container, and accompanied with a QAF-002 Material Hold Tag. 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.

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 unique packaging 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.

Use As Is – Indicates that a customer requirement nonconformance exists, but has been deemed inconsequential. Dispositions of Use As Is require the approval of the Design Authority. The Design Authority must be notified of the nonconformance and a waiver request initiated. Once the Design Authority has approved the waiver, the disposition can be completed and the parts can be moved to the next process.

Ok to Proceed – Indicates that an internal specification nonconformance exists, but has been deemed inconsequential. A waiver request does not be initiated and OK to Proceed will be authorized using the QAWI-90R Non-Conforming Material Disposition Chart. Once the parts have been dispositioned 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 correct the nonconformity;
b) 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.
   - Containment: When a customer or Witco places a product on containment, the following actions will apply:
     1. Check for additional nonconforming product still in processes or inventory.
     2. Institute a 100% inspection requirement until the cause of the nonconformity can be eliminated.
     3. Notify, in a timely manner any concerned parties (e.g. customer or supplier) if it is suspected that nonconforming product has been shipped.
c) informing the customer;
d) authorizing its use, release or acceptance under concession by a relevant authority and/or customer.

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.

Counterfeit, or suspect counterfeit, parts will be identified and segregated per the Containment process and dispositioned as scrap to prevent reentry into the supply chain.

Nonconforming product will be subjected to re-verification to demonstrate conformity utilizing the First Piece Inspection and Final Inspection processes spelled out in Section 8.6 Release of Products and Services.

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

8.7.2 Witco will retain the following documented information:

a) description of the nonconformity;
b) description of the actions taken;
c) description of concessions obtained;
d) identifies the authority deciding the action to be taken.

Documented information will be maintained for incidents that result in the creation of unanticipated nonconforming parts through the Issues Log for management evaluation (see Issues Log).

9 PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Witco has determined:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation to ensure valid results;
c) when monitoring and measuring will be performed;
d) when monitoring and measurement will be analyzed and evaluated.

QMS:
Witco evaluates the performance and effectiveness of the QMS using KPI's, MRM and internal auditing. Documented information is retained, mostly in the Issues Log, as evidence of performance and effectiveness.

Each of Witco's QMS processes will be monitored and measured. If the Process Effectiveness Goal is not met, a corrective action will be created in the Issues Log. These objectives can be located on the Key Performance Indicators (KPI's) cover worksheet.

Products and Services:
Witco evaluates the performance and effectiveness of products and services using inspection processes. Documented information is retained on inspection reports as evidence of performance and effectiveness.

9.1.2 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 daily communication, the Issues Log and KPI's.

At a minimum, Witco will monitor product conformity, on-time delivery performance, customer complaints and customer returns. Corrective action requests will be monitored and evaluated through the Management Review process. We utilize the MRM and Corrective Action 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 internal audits.

9.1.3 Analysis and Evaluation

Witco analyzes and evaluates data and information arising from monitoring and measurement.

Witco's analysis of data provides information relating to:

a) conformity to product requirements using KPI's, inspection documentation, Shop Prints, Process Drawings, customer purchase orders, etc.;
b) the degree of customer satisfaction using KPI's and the Issues Log;
c) performance and effectiveness of the QMS using KPI's, MRM and internal audits;
d) if planning has been implemented effectively using MRM, KPI's and internal audits;
e) the effectiveness of actions taken to address risks and opportunities using the Action Log and internal audits as appropriate;
f) performance of external providers using KPI's and the Issues Log;
g) the need for improvements to the QMS using MRM, KPI's, and internal auditing.

9.2 Internal Audit

9.2.1

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

a) conforms to:
    a. Witco's QMS requirements;
    b. the requirements of this International Standard;
b) is effectively implemented and maintained.

9.2.2 Witco has:

a) planned, established, implemented and maintains an internal audit process that includes its frequency, method, responsibilities, planning requirements and reporting, will consider the importance of the process being audited, changes that affect the organization and the results of previous audits;
b) defined the audit scope and criteria;
c) selected auditors and conduct audits to ensure objectivity and impartiality;
d) ensure the results are reported to management through the Issues Log or during MRM;
e) take appropriate correction and corrective actions without delay;
f) retain documented information as evidence of the implementation of the audit process and its results.

Internal Audit Process
Overview 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 or any other section they may be involved within this QMS Manual. Auditor Selection Witco Internal Auditors: Must have at least 6 months of experience at Witco or have previous experience in auditing. All auditors must be trained on the AS9100 standard and the Internal Auditing section of the QMS Manual.

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 and in-process documented information to ensure that they are being completed according to direction, with no spaces left blank. This is also a review to determine if the documented information being created, filed and retained are in accordance with their associated procedure or instruction and Section 7.5 Documented Information.
- 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 Work Instruction

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 7.5 Documented Information.

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.

9.3 Management Review

9.3.1 General

Top management will conduct Management Review Meetings (MRM) annually to ensure the QMS is suitable, adequate, effective and aligns with Witco's strategic direction/plan.

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, it will be discussed and appropriate action assigned.
2. Schedule and conduct a meeting with management personnel to discuss review inputs and determine if management action needs to 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.

9.3.2 Management Review Inputs

Management review is planned and carried out taking into consideration:

a) status of actions from previous MRM's;
    1. 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.
b) changes in external and internal issues that are relevant to the QMS;
    1. Managerial Input – this information can be obtained from internal audits, employee suggestion, etc.
    2. This includes revisions to the QMS standards, including the Quality Policy, KPI's and organizational strategic alignment, 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.
c) information on the performance and effectiveness of the QMS including:
    1. customer feedback;
        i. Issues Log
    2. the extent to which quality objectives have been meet;
        i. KPI's
    3. process performance and product conformity;
        i. KPI's
    4. nonconformities and corrective actions;
        i. Issues Log
    5. monitoring and measurement results;

        i. KPI's
    6. results of audits;
        i. internal audit reports
    7. the performance of external providers;
        i. KPI's
    8. on time delivery performance
        i. KPI's

d) the adequacy of resources;
    1. Managerial Input – this information can be obtained from internal audits, employee suggestion, etc.
e) the effectiveness of actions taken to address risks and opportunities;
    1. Audit failures
f) opportunities for improvement.
    1. Managerial Input – this information can be obtained from internal audits, employee suggestion, etc.

9.3.3 Management Review Outputs

The outputs of management review include decisions and actions related to:

a) opportunities for improvement;
b) needed changes to the QMS;
c) resource needs;
d) risks identified.

Witco retains documented information as evidence of the results of management review using ADF-70A Witco Inc. Meeting Agenda – Management and the appropriate Log. The Log will provide information on product conformity, corrective action, preventive action, internal audits, customer feedback, supplier problems and internal issues that can affect process performance.

10 IMPROVEMENT

10.1 General

Witco determines and selects opportunities for improvement and implements any actions to meet customer requirements and enhance customer satisfaction.

This includes:

a) improving products and services to meet requirements using the Operational Planning Process and the Issues Log and addresses future needs and expectations during MRM;
b) correcting, preventing or reducing undesired effects through corrective and preventive action, Risk Assessment, Action Log and MRM;

c) improving the performance and effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, Action Log and management review.

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

10.2 Nonconformity and Corrective Action

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

10.2.1 When a nonconformity occurs, including any arising from complaints, Witco:

a) reacts to the nonconformity and, as applicable;
    1. takes action to control and correct it;
    2. deals with the consequences;
b) evaluate the need for action to eliminate the causes of the nonconformity so it does not reoccur elsewhere;
    1. reviewing and analyzing nonconformities;
    2. determining the causes of nonconformities, including those related to human factors;
    3. determining if similar nonconformities exist or could occur;
c) implementing action needed;
d) reviewing the effectiveness of the corrective action taken,
e) updating risks and opportunities determined during planning, if necessary,
f) making changes to the QMS as necessary;
g) flowing down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
h) taking specific actions when timely and effective corrective actions are not achieved.

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.

Corrective Actions are appropriate to the effects of the nonconformities encountered.

Witco maintains the Corrective Action Process that defines the nonconformity and corrective action management process.

Corrective Action Process
1) A process or product nonconformity is discovered. All customer returns will have corrective action assigned. In some cases, management review of the Issues Log will lead to assignment of corrective action in an effort to improve customer satisfaction and Witco's QMS.

2) Control, correct and deal with the consequences of the nonconformity. In cases of product nonconformity, normally the Control of Nonconforming Product process is utilized.
3) The nonconformity is reviewed and analyzed, usually by a team, to determine to the root cause of the problem and if similar nonconformities could exist.
    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.
    b. 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?
4) 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. Action must be taken to correct the cause of the nonconformity (corrective action) and if the nonconformity was discovered by the customer, action must be taken to correct the problem with detection of the nonconformity prior to shipment.
    a. NOTE: When it's determined that an external provider is responsible for a nonconformance, Section 8.7 Supplier Caused Nonconformity Process will be followed and corrective action activity may be flowed down.
5) Complete the CAR form in Witco Shop ensuring all relevant planning and QMS documents are updated, including risks and opportunities, appropriately to ensure actions are implemented correctly.
6) A review of effectiveness will be conducted. 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.

10.2.2 Witco retains documented information in the Issues Log as evidence of:

a) the nature of the nonconformity and actions taken;
b) the results of any corrective action.

10.3 Continual Improvement

Witco continually improves the suitability, adequacy and effectiveness of the QMS through management review, the Action Log, KPI's, internal audits, customer complaints, employee suggestions, operational planning, risk management, changes in customer requirements and the corrective action process.

Witco considers the results of analysis and evaluation and the outputs from management review to determine if there are opportunities for improvement.

Witco monitors continual improvement opportunities through the Action and Issues Logs and evaluates their effectiveness through auditing.

Continual Improvement Process
1) The need for continual improvement is identified from management review, KPI's, internal audits, customer complaints, employee suggestions, operational planning, risk management, changes in customer requirements, corrective action process or any other medium. 2) Witco will consider the value of each improvement. Customer satisfaction shall be given extra weight in the consideration of value. 3) Once an improvement is identified, management will determine a course of action to implement the action. 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 4) All improvements are entered into the Action or Issues Logs and are reviewed by the Management Team. The Management Team must approve the issue resolution before it can be considered complete. 5) Once an improvement action has been deemed complete, it will be audited or verified for effectiveness. 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 improvement is completed to verify its effectiveness. If it is determined that the improvement resolution was not effective, then the audit is marked "Failed" and a new improvement issue is generated.

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 10.2 Nonconformity and 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 Witco.

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 requests, 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.

Action Log

Each department has been assigned an Action Log that spells out Witco's Objectives, their Process Objectives and KPI's. This information is included so management can understand the context of the organization and keep actions strategically aligned.

Only managers have access to the Action Log so business actions, risks and opportunities can be communicated, documented, implemented and evaluated for effectiveness in confidentiality.