

Quality Manual



Note: This document is a non-controlled copy of the FALCO ELECTRONICS quality manual. Falco's policy statements are written in Spanish. Each policy has its own revision level as reported in this document. This document is referred to as the Falco Quality Manual as of February 13, 2001.

Policy: MANAGEMENT RESPONSIBILITY

(Rev: C3, 06/18/98)

1.1 QUALITY POLICY

Quality means fitness for intended purposes in all aspects of activities. FALCO will strive to meet the needs of its customers more effectively than its competitors through the continuous process of quality improvement.

It is FALCO's policy: *"To manufacture and market electronic transformers, inductors and coils which comply with the customer's needs and the designer's specifications".*

This quality manual has been formulated to serve as a reference base for the policy and procedures for quality assurance and controls within FALCO. The quality system is designed to ensure the compliance of product quality standards through the evaluation, inspection, and verification at all stages of manufacturing.

Falco's Management shall define and review at least once a year the quality objectives. These are to be published for all personnel knowledge and commitment.

Responsibility for the implementation of this policy has been delegated to all staff through their management. Compliance with the provisions of this manual and commitment with quality objectives are mandatory on all personnel.

1.2 ORGANIZATION RESPONSIBILITY

FALCO has appointed the Quality Assurance Manager to be responsible for the implementation of the Quality Policy, and has the necessary authority to execute such responsibilities. The structure of FALCO is shown in the overall organizational chart maintained by Human Resources.

Management responsibilities are defined as annexed; responsibilities for other positions are fully detailed in the relevant job descriptions held by the Human Resources Department.

1.3 MANAGEMENT REVIEW

In order to maintain an effective Quality Assurance System, an internal audit of all procedures that effect the quality of FALCO products shall be undertaken.

FALCO's management with executive responsibility shall periodically review the Quality System as stated in procedure P-1-A.

Departmental Review reports shall be compiled and discussed in a Management review meeting. This meeting shall be chaired by the General Manager and shall discuss the effectiveness and achievement of FALCO's quality policy and objectives.

RELATED DOCUMENTATION

	ORGANIZATION CHART
	MANAGEMENT RESPONSIBILITIES (ANNEX)
P-1-A	MANAGEMENT REVIEW
P-17-A	INTERNAL QUALITY AUDITS

Policy: QUALITY SYSTEM

(Rev: C1, 11/14/97)

2.1 GENERAL

This quality manual complies with the requirements of International Standard ISO 9002-1994

PROCEDURES

All procedures are documented and stored in two manuals: The Quality Manual & The Procedures Manual.

The Quality Manual contains the General Policies established by FALCO's Executive Management.

The Procedures Manual contains the second and third tier documentation: Procedures, Forms, Reference Tables, Workmanship Standards, Test Methods and Design Standards.

In order that the manual reflects the current practices and requirements of the company, amendments to the manual may be

necessary, and these must be recorded.

Amendments or changes to this manual shall be done in accordance with the Document Control policy. Proposed amendments to each document in this Manual shall be submitted to its assigned responsible for consideration and approval under the documentation change control procedure (See P-5-A). The manual shall be periodically reviewed during the Internal Audits and Management Reviews to reaffirm its adequacy to the current company requirements. The distribution of this manual shall be Quality Assurance's responsibility.

A current list of all controlled copies of these manuals and their location is maintained by Quality Assurance through the QMCN Manager Information System.

2.3 PLANNING

The initial quality planning for the implementation of new products to be produced whether they are the first-time or variations of existing products shall be as specified by procedure P-5-B - Product Development & Change Procedure.

The procedures cover aspects that include; a) identifying controls, resources and skills necessary to achieve the required quality level, b) updating quality control, inspection and testing techniques as necessary, c) identifying extraordinary measurement requirements and suitable verification methods, d) clarifying standards of acceptability, e) identifying and preparing quality records.

RELATED DOCUMENTS

P-2-A QUALITY SYSTEM DOCUMENTATION STRUCTURE
P-5-A QUALITY SYSTEM DOCUMENT CONTROL
P-5-B PRODUCT DEVELOPMENT & CHANGE PROCEDURE
P-17-A INTERNAL QUALITY AUDITS

Policy: CONTRACT REVIEW

(Rev: B3, 11/08/99)

3.1 QUOTATION AND QUALIFICATION

Production Planning and Product Engineering are responsible to establish and maintain documented procedures for quotation and qualification of parts.

3.2

During the quotation and qualification stage the primary consideration is to assure that:

- a) customer requirements are correctly interpreted.
- b) a review is performed to verify that all requirements are clearly understood.
- c) that any differences from the customer requirements are documented, approved by the customer and communicated to the functions involved.

3.3 ORDER ENTRY

Production Planning are responsible to establish and maintain documented procedures for the coordination and review of orders placed by customers.

3.4

Each customer order shall be reviewed to insure that:

- a) requirements are adequately defined and documented.
- b) any differences between the purchase order and the quotation is resolved.
- c) capabilities to meet the purchase order requirements are verified and confirmed.

3.5 AMENDMENT TO A CONTRACT

Amendments are done and logged in the FOMICSI (main database). Where necessary, records are transferred by electronic means (e-mail).

RELATED DOCUMENTATION

P-3-B ORDER ENTRY
P-5-B PRODUCT DEVELOPMENT & CHANGE PROCEDURE

Policy: DESIGN CONTROL

(Rev: B1, 11/10/99)

4.1

Initial design data: Product Engineering, Manufacturing Engineering, Quality Control, and Sales have processes and procedures in place

to elaborate designs according to customer requirements. Such customer requirements are documented and transmitted via a SALES ENGINEERING REQUEST (SER). A prime focus is placed upon improving the manufacture-ability of our components onto our customer's boards and within their manufacturing processes.

4.2

Verification and validation of the design: Product Engineering, Manufacturing Engineering, Quality Control, and Sales have established procedures and systems in place (FSM: FALCO SALES MODULE) to control the design changes. The validation of the design is done through the FAIFORM: FIRST ARTICLE INSPECTION SHEET.

4.3

Product Engineering, Manufacturing Engineering, Quality Control, and Sales are responsible to elaborate, maintain and control all the documentation related to the design of a product through a SAMPLE#, Catalogue Part Number (CPN) and/or Falco Part Number (FPN). This applies to external documents (ie. Customer drawings, industrial standards and norms, IML: ITEM MASTER LOG – Falco internal drawing, etc).

4.4

Design Changes and Reviews: Product Engineering establishes and maintains a master list of documents that are essential for the correct functioning of the quality system with regards to design control. Each document essential for the correct functioning of the quality system has its own procedure to assure that:

all changes made during the lifetime of the design are properly documented and that they are clearly understood.

the current revision level is clearly understood as well as its current standing.

the appropriate personnel has reviewed and approved the change. This process takes place through an ECN: ENGINEERING CHANGE NOTICE.

each document has been properly elaborated according to established procedures and norms and that such document is distributed to each corresponding area as specified by the procedures.

the method of disposition of invalid or obsolete documents is defined.

RELATED PROCEDURES

P-5-A QUALITY SYSTEM DOCUMENT AND DATA CONTROL

P-5-B PRODUCT DEVELOPMENT & CHANGE PROCEDURE.

P-5-C MATERIAL DEFINITION & CHANGE PROCEDURE

P-8-B IDENTIFICATION AND TRACEABILITY OF FPNs

P-16-A QUALITY RECORDS

Policy: DOCUMENT AND DATA CONTROL

(Rev: A4, 04/30/97)

5.1

Product Engineering shall create, maintain and control all product design documentation, workmanship standards, and raw material documentation.

Manufacturing Engineering shall create, maintain and control all documents necessary to manufacture the product.

External documentation that may be necessary for Product or Material definition shall be controlled by Product Engineering (i.e. customer prints, industry standards). External documentation related to the Quality Assurance System shall be controlled by Document Control (i.e.: ISO Standards., Customer or third party audit reports, etc.).

5.2

Document Control shall establish and maintain a master list of documents that are essential to the correct functioning of the quality system.

Procedures for every specific document that is essential to the effective function of the quality system, shall be established to:

a) ensure that the methods of how changes are identified are explained so that changes can be easily reviewed.

b) explain where the current revision is located on the document.

c) ensure that the proper personnel has reviewed and approved the introduction or change.

d) ensure that the document is properly elaborated and distributed to every location that requires the information for the correct function of the quality system.

e) define the disposition of invalid and/or obsolete documents.

RELATED PROCEDURES

P-5-A QUALITY SYSTEM DOCUMENT AND DATA CONTROL

P-5-B PRODUCT DEVELOPMENT & CHANGE PROCEDURE.

P-5-C MATERIAL DEFINITION & CHANGE PROCEDURE

Policy: PURCHASING

(Rev: A5, 11/08/99)

6.1

Product Engineering shall establish and maintain documented procedures to ensure that purchased products conform to specified requirements.

6.2

Source and component selection, evaluation, and qualification is the responsibility of Product Engineering.

Suppliers are selected based on their ability to meet all the contractual, product requirements, and with particular emphasis on quality.

FALCO predominately purchases catalogue items from industry recognized sources and defines the items as Falco Stock Numbers.

FALCO demands that every vendor accepts the terms and conditions under which FALCO operates as specified in the SUPPLIER GUIDE. A copy of such acceptance shall be kept by Purchasing .

FALCO inspects all incoming material regardless of the vendor's standing, reputation, or quality record.

All components are qualified either by the examination of samples or the usage of such components in products (FPNs) and qualified during the elaboration of the First Article Record to document the compliance with the Customer requirements. If any parameter cannot be verified, documented evidence is requested from the vendor.

6.3

Purchasing documents shall contain data clearly describing the product ordered, quantities desired and dates required.

Purchasing documents shall ensure that any special requirements, such as special processes, test data, and certificates of compliance, are clearly communicated to the vendor.

Purchasing documents shall reflect any specific inspection arrangement.

Purchasing documents shall be reviewed and approved for adequacy by responsible personnel prior to release.

6.4

Verification and acceptability of incoming material is the responsibility of Incoming Inspection.

Purchased material, equipment, or services shall be verified and inspected to assure that FALCO and any specific customer requirements are met.

In the cases in which verification of purchased product is to be made at the vendors premises, FALCO shall specify the arrangement in the purchasing documents.

In cases which contractual requirements allow the customer to verify the vendor's premises to certify the quality of the product, such verification shall not be used by FALCO as evidence of effective control of quality by the vendor. Nor shall such inspections absolve FALCO from providing acceptable product.

RELATED PROCEDURES

P-6-A	SOURCE AND COMPONENT SELECTION & ASSESSMENT
P-6-B	PURCHASE ORDERS. DOCUMENTING & ISSUING
P-10-A	INCOMING INSPECTION
SUPPLIER GUIDE	PURCHASING DEPARTMENT

Policy: CUSTOMER SUPPLIED PRODUCT

(Rev: A2, 08/31/96)

7.1

The policy of FALCO is to avoid the use of customer-supplied raw materials. If any raw material is supplied, FALCO assumes the full responsibility for such product.

7.2

Verification and storage of any customer-supplied raw material, shall be managed in the same manner as other products. If required, all shrinkage and scrap of such product shall be recorded and reported to the customer.

7.3

The policy of FALCO is to avoid the use of customer-supplied equipment. If any equipment is supplied FALCO assumes the full responsibility for such equipment.

7.4

Storage and maintenance of any customer-supplied equipment, shall be managed in the same manner as other comparable equipment.

RELATED DOCUMENTATION

P-6-B PURCHASE ORDERS, DOCUMENTING & ISSUING
P-10-A INCOMING INSPECTION

Policy: PRODUCT IDENTIFICATION AND TRACEABILITY

(Rev: A2, 08/31/96)

8.1

Raw material, work in process, and finished goods shall be identifiable and traceable.

8.2

Raw materials shall be identified by their part number (FSN), revision level, and receiving date.

8.3

Work In Process shall be traceable to a shop traveler which is tied to a Work Order containing a specific revision level. Each revision level is traceable to a set of product documentation.

8.4

Finished goods shall be traceable to a specific drawing revision (IML), and the quality final inspector.

8.5

If a customer requires parts traceability, the individual parts will be labeled with the relevant information as specified by the customer purchase order.

RELATED DOCUMENTATION

P-10-A INCOMING INSPECTION
P-8-B FPN IDENTIFICATION & TRACEABILITY
P-8-C PRODUCT LABELING

Policy: PROCESS CONTROL

(Rev: B3, 04/05/97)

9.1

Product Engineering is responsible to create, maintain and implement all Workmanship Standards. A list containing the Standard's name, revision and date of issue shall be maintained.

9.2

Manufacturing Engineering is responsible to generate the Product Sheet Instructions, General Process Procedures, and to control and maintain all machinery, equipment and fixtures.

9.3

The production process shall be carried out under controlled conditions. Controlled conditions shall include the following:

- a) the method of production and/or process for every Falco Part Number (FPN) shall be determined by the Item Master Log (IML), List of Operations (LOP), Bill of Material (BOM), Process Sheet Instructions (PSI), applicable General Process Procedures and related Workmanship Standards.
- b) the machinery, equipment, and fixtures used for the production of a product shall be specified, and shall be controlled and maintained to ensure continuous process capability.
- c) criteria of workmanship shall in general be as mandated in the Workmanship Standards, or as specifically called for in the Item Master Log or Product Sheet Instructions.
- d) all generic processes shall be covered in General Process Procedures.
- e) all monitoring and checking of parameters shall be specified in the Item Master Log and shall be assigned to Quality Assurance to ensure the intended quality through final audits. In-process monitoring and checking shall be the responsibility of Quality Control and Line Supervisors.
- f) compliance with the Item Master Log, List Of Operations, Process Sheet Instructions General Process Procedures and Workmanship Standards shall be audited and reviewed.

9.4

Special Processes are those which can not be fully verified by subsequent inspections and testing of the product.

- a) Only specially trained and qualified personnel is allowed to perform such functions.
- b) Continuous monitoring and or compliance with documented instructions is required to ensure that the specified requirements are met.
- c) Appropriate records shall be maintained to ensure product traceability to material, revision and personnel.

9.5

Control shall be maintained over all capitalized equipment. Every piece of equipment shall have its own Specification sheet, Operating Manual, and Preventive Maintenance Record. This is to ensure that the equipment's characteristics and limitations are known.

RELATED DOCUMENTATION

P-9-A	PROCESS SHEET INSTRUCTIONS
P-9-B	IN-PROCESS TEMPORARY CHANGES. DEVIATIONS
P-9-C	TOOLING, JIGS & FIXTURE CONTROL
P-10-B	IN-PROCESS INSPECTION

WORKMANSHIP STANDARDS.

Policy: INSPECTION & TESTING

(Rev: A3, 08/31/96)

10.1

Product Engineering is responsible to establish and maintain documented procedures of inspection and testing in order to assure that all incoming material and manufactured product specifications are achieved.

Personnel doing inspections and testing activities shall be qualified by Product Engineering.

The Inspection program shall include the inspection of raw materials, in-process audits and final audits.

10.2

Acceptance criteria for every Falco Stock Number (FSN) shall be specified as well as the quantity and type of tests to be performed to certify that the acceptance criteria is met.

All incoming material may not be used or processed until it has been accepted by Incoming Inspection.

It is not the policy of issuing non-inspected material to the floor. If such event were to occur the material will be identified so that traceability will be maintained.

10.3

In-process inspections are defined by Product Engineering and carried out by Quality Assurance for all parameters that cannot be tested in the final audits. They shall include, but shall not be limited to; transformer turns testing, IEC-950 safety requirements and winding quality.

In-process testing is defined by Manufacturing Engineering and carried out by either Production or Quality Control depending on the type of test.

All parts that fail testing shall be segregated and identified. The parts may move to the next step only if they meet the testing requirements.

10.4

Quality Assurance shall carry out the final inspection audit to certify that the product meets all the specific requirements.

Quality Assurance shall verify that all test operations have been completed and the necessary data has been gathered and documented.

When any product fails to pass any inspection criteria a Reject Report will be generated to control the disposition of such product.

RELATED DOCUMENTATION

P-10-A	INCOMING INSPECTION
P-10-B	IN-PROCESS INSPECTIONS
P-10-C	FINAL INSPECTION

Policy: INSPECTION, MEASUREMENT & TEST EQUIPMENT

(Rev: A3, 10/23/96)

11.1

FALCO controls, calibrates and maintains test equipment and measuring devices used to certify that the product conforms with the specified requirements.

11.2

All equipment that can affect product quality is identified and calibrated against a NIST traceable standard. The Portable Transfer Standard method is adopted whereby only critical equipment and standards are externally calibrated and then used to calibrate internal equipment. Any Portable Transfer Standard shall generally be an order greater in its measurement capability than the equipment being checked. When no recognized standard exists the basis used for calibration shall be documented.

11.3

Only equipment that is capable of the required accuracy and precision of the measurement to be taken is used. In general the accuracy of the equipment must be equal or less than 10% of the tolerance.

11.4

Equipment that is used for in-process measurement need not be calibrated, provided that the measurements made are not the last opportunity to record some item that is a deliverable specification.

11.5

If any equipment is found to be out of calibration the equipment shall be removed, tagged, and sent for adjustment. Documented procedures shall ensure that the validity of previous inspections are guaranteed when test equipment is found to be out of calibration.

11.6

All test equipment that does not require calibration shall be identified with a "CALIBRATION NOT REQUIRED" sticker.

11.7

Test Equipment Definition Sheets shall insure that;

- a) the characteristics of the equipment, frequency of checks, check method, and acceptance criteria are identified,
- b) environmental conditions are suitable for the usage of the equipment,
- c) the handling, preservation and storage of the equipment is adequate to guarantee the accuracy and fitness,
- d) safeguard that adjustments which would invalidate the calibration settings do not occur.

11.8

The Calibration & Location record shall insure;

- a) how the equipment is identified,
- b) how the location of equipment is known at any time,
- c) how to detect the calibration status,
- d) that calibration results are maintained.

RELATED DOCUMENTATION

P-11-A	LABORATORY & TEST EQUIPMENT DEFINITION AND CONTROL
P-11-B	TEST EQUIPMENT CALIBRATION PROCEDURE
P-9-C	TOOLING, JIGS & FIXTURES CONTROL

Policy: INSPECTION & TEST STATUS

(Rev: A2, 08/31/96)

12.1

The inspection and test status of any raw material or product shall be easily identified to ensure that only accepted product has been used.

12.2

Incoming Inspectors, Quality Control Inspectors and Quality Assurance Inspectors are the only personnel authorized to make such identifications.

12.3

Identification of verification status shall be by a suitable means such as stamps, tags, notations, inspection records that accompany the product, computer entries, and/or physical location.

12.4

The status shall clearly indicate if the parts have been inspected, accepted, on hold awaiting decision, or rejected.

RELATED DOCUMENTATION

P-10-A	INCOMING INSPECTION
P-10-B	IN-PROCESS INSPECTIONS
P-10-C	FINAL INSPECTION

Policy: CONTROL OF NONCONFORMING PRODUCT

(Rev: A3, 11/28/97)

13.1

Procedures to deal with nonconforming product should be taken as soon as indications occur that materials, components and completed products do not or may not meet the specified requirements.

13.2

Raw material (FSN) and products (FPN) that do not conform to specified requirements shall be identified, documented, segregated, and given a disposition.

13.3

The Production Manager, Process Engineering representative, and Quality Control are responsible for resolution of non-conforming product (FPN) and assure that it is prevented from unintended use.

13.4

Quality Control, Purchasing, and Product Engineering are responsible for the resolution of nonconforming raw materials (FSN).

13.5

Disposition of material and product shall be limited to "Use as Is", rework, sort, scrap or return.

13.6

Only parts that meet the customer requirements shall be shipped. If nonconforming parts are to be manufactured and shipped, a deviation will be requested from the customer prior to shipping.

13.7

Records of nonconforming items and their disposition shall be maintained.

RELATED DOCUMENTATION

P-10-A	MATERIAL INCOMING INSPECTION
P-10-B	IN-PROCESS INSPECTION
P-10-C	FINAL INSPECTION
P-10-D	IN-PROCESS PRODUCT TESTING
PG-SCRAP	SCRAP CONTROL.

Policy: CORRECTIVE & PREVENTIVE ACTIONS

(Rev: A2, 08/31/96)

14.1

Corrective and preventive actions shall be carried out as required.

14.2

Coordination, recording, and monitoring of corrective actions related to all aspects of the quality system is assigned to Quality Control and Product Engineering. The analysis and implementation shall be assigned to the appropriate function on a case by case basis.

14.3

Procedures for corrective actions shall insure that;

- a) customer complaints and nonconformity reports are effectively handled,
- b) an investigation and analysis of the problem is carried out and the results are recorded,
- c) the most effective corrective actions are taken,
- d) controls are placed to ensure that the corrective action is applied and effective.

14.4

Procedures for preventive actions shall insure that;

- a) potential causes of nonconformities are identified through work processes, audit results and quality records,
- b) the method of how to resolve the preventive action is determined,
- c) the most effective preventive actions are taken,

- e) controls are placed to ensure that the preventive action is applied and effective,
- f) information on actions taken is submitted for management review.

RELATED DOCUMENTATION

P-14-A	CORRECTIVE ACTIONS REQUESTS
P-14-B	SUPPLIER CORRECTIVE ACTIONS REQUESTS
P-14-C	PREVENTIVE ACTIONS

Policy: HANDLING, STORAGE, PACKAGING & DELIVERY

(Rev: B1, 11/08/99)

15.1 GENERAL

Documented procedures shall guarantee that handling, storage, packaging, preservation and delivery of raw materials and products is done according to specified requirements.

15.2 HANDLING & STORAGE

Handling and storage of Raw Materials shall be as specified by Table FSN_ALM. Any special handling and storage requirement for products (FPNs), shall be specified in the Process Sheet Instructions.

15.3 PACKING & MARKING

Parts are packed in boxes which contain cell partitions. Parts are packed as specified by Item Master Log (IML).

Instructions on how to mark parts is provided by the Sales Engineering Request (SER) document corresponding to each customer and customer revision. Parts shall primarily be identified in two manners; color coding or labeling. The labeling information for every part number is located on the Sales Engineering Request (SER) and transmitted to the corresponding Work Order. Any color coding scheme is identified on the Item Master Log (IML).

All boxes shall be SERIALIZED so that the product can be easily identified. Each box is labeled with the following information; customer name, customer part number and revision, customer purchase order number, quantity, weight, date code of manufacture, Falco Part Number, Falco IML Revision Level, Customer Order Number, and Label Information.

Packaging shall be in the tolerance of the capacity of the box and pallet. The IML for each FPN specifies the materials (box and pallet) used for packaging. The corresponding MMES for each box (FSN) describes its specifications and capacity.

15.4 PRESERVATION

While parts are under FALCO control, all necessary steps are to be taken to ensure that parts are preserved.

15.5 DELIVERY

All boxes sent by Air Freight are sent as loose cargo. All boxes sent by truck or boat are placed on a skid. All pallets are serialized by number in order to provide traceability and control. All shipments leaving the plant are serialized in sequential number.

RELATED DOCUMENTATION

FSN_ALM Table : HANDLING & STORAGE OF RAW MATERIALS	
P-15-A	PACKAGING, MARKING & DELIVERY OF FINISHED PRODUCT
PG-SOLD SOLDERABILITY.	

Policy: QUALITY RECORDS

(Rev: A3, 06/21/98)

16.1

Every Department Head or Manager shall establish and periodically review, procedures for identification, access, filing and disposition of records that pertain to the quality system.

16.2

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the Quality System.

Pertinent quality records from any vendor shall be an element of the quality records.

16.3

Individual procedures that refer to any quality record shall include a section that specifies;

- a) who is responsible to generate and complete the record,
- b) how and where it is filed,
- c) who has access to the record,
- d) how long it will be maintained at each step of the storage cycle.

16.4

The following criteria shall be used in establishing of the quality records system;

- a) records shall be legible and identifiable.
- b) stored in a retrievable way.
- c) placed in a suitable environment to prevent deterioration, damage, or loss.
- d) prevent lost or modifications by unauthorized personnel.
- e) after the specified retention time, records shall be discarded. When the information contained might be considered as classified, records shall be destroyed (shredded).

When electronically stored and maintained, records shall have a documented procedure that describes the backup method according to the above criteria.

When agreed contractually, quality records shall be made available for evaluation by the customer or his representative for an agreed period.

RELATED DOCUMENTS

P-16-A QUALITY RECORDS MASTER LIST
P-16-B DATA BACKUP & PURGE PROCEDURE
FORMAS SECTION 3 OF THE QUALITY ASSURANCE MANUAL

Policy: INTERNAL QUALITY AUDIT

(Rev: A3, 04/05/97)

17.1

A comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the Quality Assurance program.

17.2

In the establishment of this activity the following considerations shall be incorporated:

- a) audits are conducted by qualified personnel independent from those having direct responsibility in the areas being audited.
- b) the audit team shall have a lead auditor as part of the team or shall review the results of the audit.
- c) audits are performed according to a written procedure and check lists.
- d) the audit shall include the process, product, and documentation.
- e) the audit report will be reviewed by persons responsible in the area being audited and will be kept by the ISO Management Representative.
- f) corrective actions will be required where items or activities are found to be nonconforming.
- g) following audits will be conducted to verify that actions have been taken and that these actions have been effective.

17.3

Audits are under the responsibility of the General Manager and are scheduled based on the status and importance of the activity.

RELATED DOCUMENTATION

P-17-A INTERNAL QUALITY AUDITS

Policy: TRAINING

(Rev: B2, 08/31/96)

18.1

Quality control starts with training and ends in training. Training is conducted regularly for top management, middle management, and workers. Understanding what to do and how to do it is fundamental to the achievement of quality.

18.2

FALCO provides training to all personnel performing activities affecting quality.

Training shall be given to technical personnel to enhance their contribution to the success of the quality system.

18.3

Training programs shall ensure that personnel maintain up-to-date knowledge and techniques in the area of assigned responsibility.

Training shall be provided at all levels with regard to the Quality Plan Elements as they effect each respective area.

18.4

Training shall be conducted on the use of equipment to ensure that each individual who uses an instrument, tool, or piece of machinery, knows how to properly use it.

Training shall be conducted about the documented procedures, work instructions, and workmanship standards, that process supervisors and operating personnel receive.

Training shall be formally conducted by qualified personnel, with special time periods allotted for the activity.

18.5

Training records shall be maintained by Human Resources for all levels of individuals. The purpose of training records is to prove the all individuals are qualified to perform their jobs.

If re-qualification or re-certifications are required a tickler system must be developed to allow appropriate time for the process.

RELATED DOCUMENTATION

P-16-A QUALITY RECORDS MASTER LIST.

Policy: SERVICING

(Rev: A2, 08/31/96)

19.1

No parts manufactured by FALCO require to be serviced in any manner; therefore this ISO section is not applicable.

Policy: STATISTICAL TECHNIQUES

(Rev: C2, 03/07/00)

20.1

Where appropriate, statistical techniques are to be used to verify the acceptability of process capabilities, Materials (FSNs) and Products (FPNs).

20.2

For Material acceptance the table C = 0 is used to obtain the corresponding sample size as per the AQL values stated in the FSN documentation (Incoming Inspection Sheet - P-05-A-7).

20.3

Statistical techniques used to verify process capabilities are:

HISTOGRAMS - Binomial distribution charts.

SCRAP PARETO CHART - Compilation of causes of scrap per part Number FPN, and can be compiled for a range of weeks.

PPM RESULTS - PPM defect level based on final audit sample findings per Part Number, department, and total company, for a range of weeks.

EFFICIENCY RESULTS - Efficiency ratings as a result of earned hour per department divided by hour paid per department and total company, can be run for a range of weeks.

20.4

The Quality Control department is responsible "Sampling procedure for inspection by attributes" (ANSI Z1.4 through Z1.9) is used to accept finished goods (see P-20-B).

HISTOGRAMS - Binomial distribution charts.

SCRAP PARETO CHART - Compilation of causes of scrap per part.

PPM RESULTS - PPM defect level based on final audit sample findings per part, department, and total company.

20.5

Final audits are carried out in lots. In-process verifications are carried out on a 100% basis for all critical parameters (see P-10-B).

20.6

Any Statistical Technique requirement shall be evaluated by the Department Head or Manager. To ensure its effective implementation and use, the involved personnel shall be trained.

RELATED DOCUMENTATION

P-5-A-7 MATERIAL INCOMING INSPECTION SHEET CONTENTS.

P-10-B IN-PROCESS INSPECTIONS.

P-20-A STATISTICAL PROCESS CONTROL

P-20-B SAMPLING PROCEDURE FOR INSPECTION BY ATTRIBUTES

PG-SCRAP SCRAP CONTROL

CO Table: C=0 SAMPLING PLANS INDEX VALUES