QUALITY MANAGEMENT SYSTEM MANUAL

AMETEK

Sensor, Test and Calibration Business Unit

Hunter Spring

PMT pressure SENSORS

DREXELBROOK

AMETEK SENSORS, TEST AND CALIBRATION BUSINESS UNIT

AMETEK Drexelbrook

205 Keith Valley Road,

Horsham PA, 19044

AMETEK PMT Products

205 Keith Valley Road,

Horsham PA, 19044

AMETEK Hunter Spring Products

205 Keith Valley Road,

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INTRODUCTION

The purpose of this manual is to explain the general procedures for the implementation of AMETEK Sensors Test and Calibration Business Unit (STCBU) AMETEK Drexelbrook, PMT and Hunter Spring Product Lines Quality System in accordance with the requirements of ISO 9001.

The basic Quality System for AMETEK STCBU is outlined in this manual. It is not intended that this manual cover all contingencies of individual contracts, but that it details the basic system used by AMETEK STCBU to control quality. Specific procedures related implement the Quality System and or specific contracts will be developed and implemented on an individual contract basis as required.

APPROVED _____ DATE:09-23-2017
Division Vice President & Business Unit Manager
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APPROVED _____ DATE: 09-23-2017
QA Manager PA Location

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Revision History

ISSUE #	DATE REVISED	REVISED BY	COMMENTS / REASON
7	7/91	SGA	Update to ISO-9001 (EDO #7-91-201)
8	5/93	SGA	Update to Comply with ISO-9001 (EDO #5-93-201)
9	6/94	SGA	Update Signature Page. Clarify Bible Notes and Incorporate Changes Due to audit by DNV-2-94. EDO # 5-94-202
10	8/95	SGA	Update ISO-9001 – 1994 Edition
11	3/99	SGA	Update Signature Page. Update 23.9.3Change M. Geary to S. Ladyansky
12	2/00	SGA	Update company change to AMETEK Drexelbrook. Update 23.9.3. Change S. Ladyansky to L.J. Kramer
13	2/02	SGA	Update minor changes sec.3.2,5.0,9.0,14.0,16.0 Delete sec. 23.0 FAA –PMA Requirements
14	7/02	SGA	Update QA Policy and Signatures, design control from 5 stages to 3 stages.
15	9/03	SGA	Update and change format to comply with ISO 9000 :2000 edition
16	11/04	SGA	Update Quality Objectives
17	4/07	SGA	Update due to organizational changes
18	10/09	SGA	Update to reflect ISO-9001:2008 Standard
19	1/13	SGA	Add training for Ex personnel
20	12/13	SGA	Update Quality Policy and Departmental Responsibilities to STBU Standard.
21	9/17	SGA	Update to consolidate PMT and HUNTER into QSM

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1. QUALITY PROGRAM MANAGEMENT

1.1 General Requirements

AMETEK STCBU has implemented a Quality Management System that is continuously maintained for effectiveness and process improvements in accordance with the requirements of ISO 9001.

1.2 Documentation Requirements

1.2.1 General

The AMETEK STCBU documentation system consists of four tiers of documentation. The first tier is the Quality Policy. The second tier is this Quality Manual which describes the quality system operating within AMETEK STCBU to meet the ISO-9001 Quality System requirement's model. The third tier are those documents which detail the instructions and procedures from which employees perform specified work plans to ensure the effective planning, operation and control of the processes required. These instructions and procedures include Quality System procedures, detailed assembly procedures, inspection and test procedures, forms, assembly drawings and specifications, and process procedures and work instructions. The fourth tier is the records required to be maintained to provide objective evidence of compliance.

1.2.2 Quality System Manual

The Division Vice President, STCBU delegates the responsibility for the preparation, distribution and maintenance of the Quality System Manual to the Quality Assurance Manager.

Copies of this manual are available to all customers of AMETEK STCBU, but specific operating instructions and procedures will be available for in-factory review only.

Controlled copies of this manual if required by contract are available from the Quality Assurance Manager.

The Q. A. Manager shall control company issued controlled copies of this manual on separate log.

Refer to Figure 1 for a description of the sequence and interactions of the process required to ensure the effective planning, operation, and control of the processes outlined by the Quality System Manual

Figure 1 (A)

QUALITY MANAGEMENT SYSTEM SEQUENCE AND INTERACTION

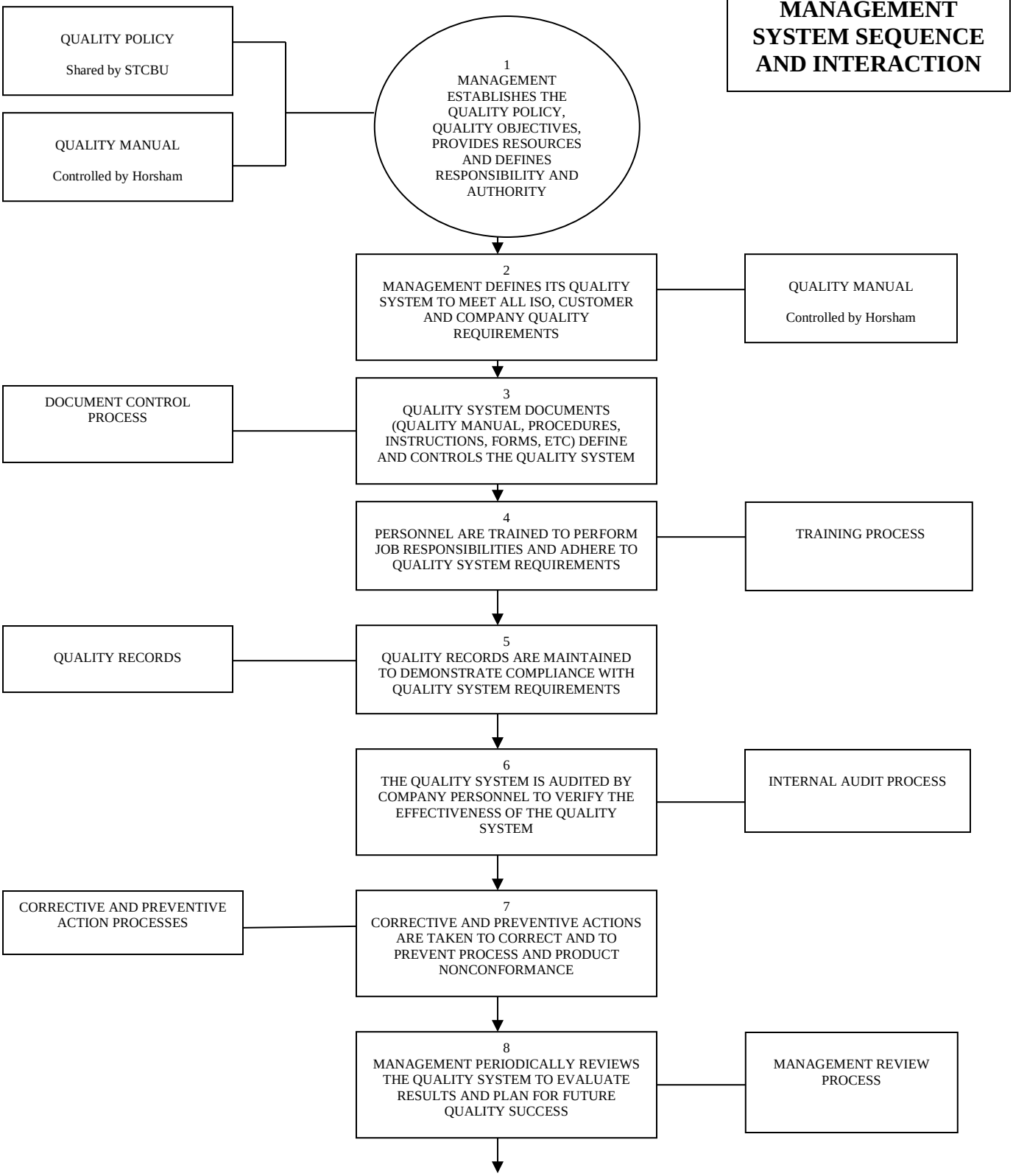
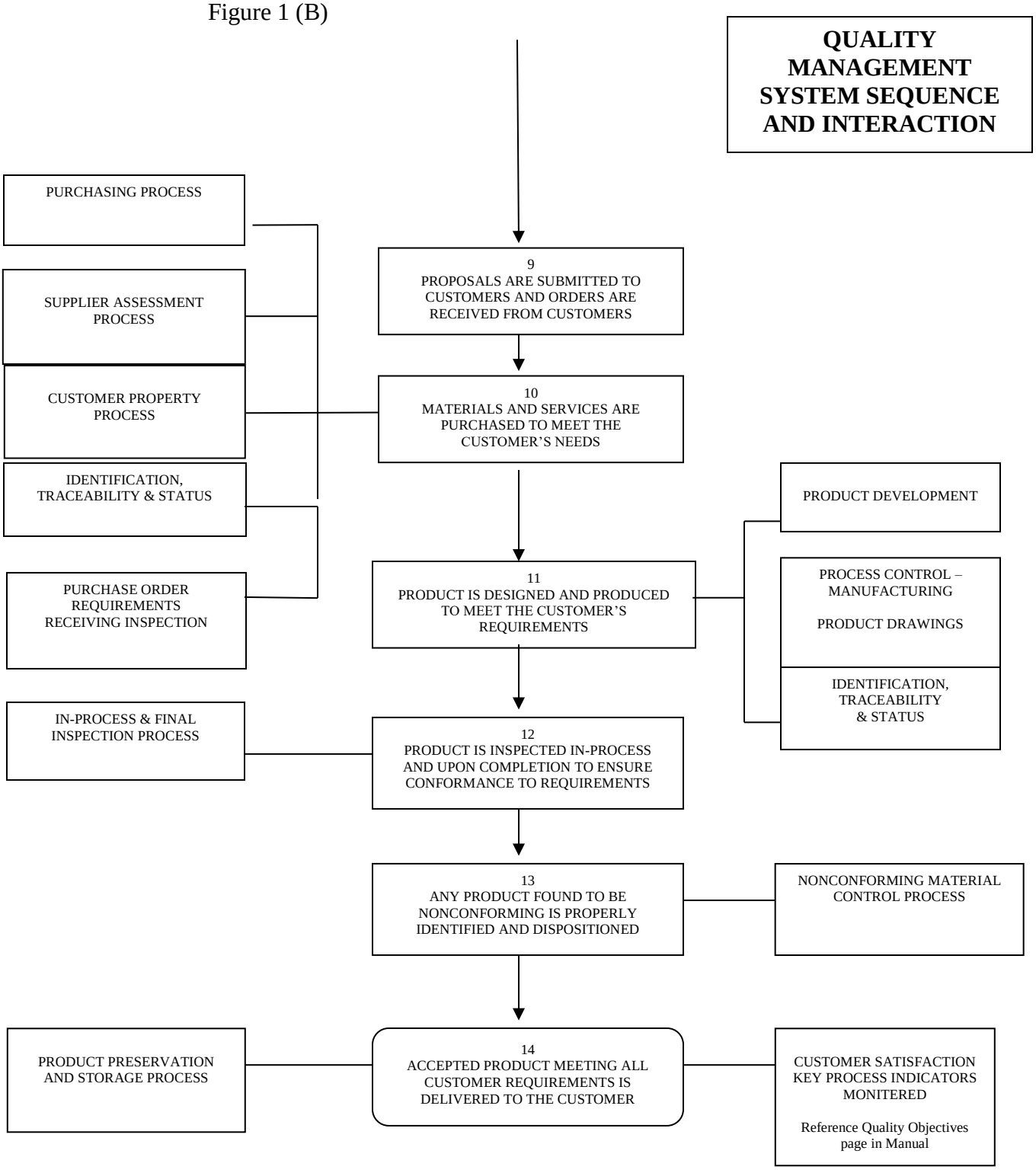


Figure 1 (B)


QUALITY MANAGEMENT SYSTEM SEQUENCE AND INTERACTION
PURCHASING PROCESS
SUPPLIER ASSESSMENT PROCESS
CUSTOMER PROPERTY PROCESS
IDENTIFICATION, TRACEABILITY & STATUS
PURCHASE ORDER REQUIREMENTS RECEIVING INSPECTION
IN-PROCESS & FINAL INSPECTION PROCESS
PRODUCT PRESERVATION AND STORAGE PROCESS
9 PROPOSALS ARE SUBMITTED TO CUSTOMERS AND ORDERS ARE RECEIVED FROM CUSTOMERS
10 MATERIALS AND SERVICES ARE PURCHASED TO MEET THE CUSTOMER'S NEEDS
11 PRODUCT IS DESIGNED AND PRODUCED TO MEET THE CUSTOMER'S REQUIREMENTS
12 PRODUCT IS INSPECTED IN-PROCESS AND UPON COMPLETION TO ENSURE CONFORMANCE TO REQUIREMENTS
13 ANY PRODUCT FOUND TO BE NONCONFORMING IS PROPERLY IDENTIFIED AND DISPOSITIONED
14 ACCEPTED PRODUCT MEETING ALL CUSTOMER REQUIREMENTS IS DELIVERED TO THE CUSTOMER
PRODUCT DEVELOPMENT
PROCESS CONTROL – MANUFACTURING
PRODUCT DRAWINGS
IDENTIFICATION, TRACEABILITY & STATUS
NONCONFORMING MATERIAL CONTROL PROCESS
CUSTOMER SATISFACTION KEY PROCESS INDICATORS MONITERED
Reference Quality Objectives page in Manual

1.2.3 Control of Documents

1.2.3.1 General

The procedures listed below describe the methods used to create new documents or to revise, update, obsolete and re-approve documents as necessary. It also ensures documents remain legible and readily available.

Review of existing documents for their effectiveness may result from the following actions including manufacturing process changes, new product development, corrective or preventative actions, customer feedback, continuous improvement actions and internal audits.

All documents are reviewed and approved for adequacy by authorized personnel before issue.

External documents are defined as industry related standards and customer supplied drawings for customer specific products. For conformance requirements, it is the responsibility of the user to verify the correct issue level of industry related standards with the issuing authority or a reliable standards source as required. Customer supplied drawing are to be controlled by engineering.

Minor, temporary, or emergency changes to existing documents are permissible provided the change is initialed and dated on the document by authorized personnel. Copies of the changed drawing shall be forwarded to all affected personnel and a copy to the responsible department for revision.

Obsolete documents, which are retained for legal or knowledge preservation purposes, are stamped or marked obsolete.

Documents are stored on the company network and available to any computer connected to the company drive or in the Engineering Department files assuring current, legible, identifiable drawings and changes thereto are available to any operating personnel.

1.2.3.2 Procedures

- Quality Management System procedures that influence the Quality Management System or the quality of products produced are developed, revised and controlled.
- Product drawings, part drawings, and data are permanent and as such, and EDO Procedure 440-0015-003 (DREXELBROOK & PMT) and EN-201-22 HUNTER Spring governs their origination, revision, and implementation. The current list of engineering documents is maintained on the company network drive or filed in the Engineering Department Drawing files.

- Manufacturing process sheets and travelers are developed, maintained, and controlled by the Manufacturing Engineering Department.

1.2.4 Control of Records

Quality records are records that have an influence on the quality of processes and material and to demonstrate the achievement of the required quality and the effective operation of the quality system.
AMETEK STCBU quality records, storage locations, and retention times are listed in Table 1 below.
Records pertaining to a specific order or contract will be available for review by the authorized customer representative.

Records shall be maintained in a manner that they are readily available and in a suitable environment to minimize deterioration or damage or to prevent loss.

Record Type	Record Description	Minimum Retention Period	How Filed	Who maintains and manages the files	Storage Medium	Location
Management Review	Ops Review Presentation Information & Action Items	3 Years	By date	QA Manager	Hard Copy	QA Manager's Office
Business Planning	Business Plans	5 Years	By date	VP/General Manager	Hard Copy	VP/General Manager's Office
Contract Review	Opportunity Proposals	3 Years	By Sales Order	Sales/Marketing Department Staff	Hard Copy or Electronic	Customer file, Sales/Mkt dept.
	Contracts and Amendments to Contracts	3 Years	By Sales Order	Sales/Marketing Department Staff	Hard Copy	Customer file, Sales/Mkt dept.
	Customer Purchase Orders	3 Years	By Sales Order	Sales/Marketing Department Staff	Hard Copy	Sales Order file, Sales/Mkt dept.
	Sales Orders & Acknowledgments	3 Years	By Sales Order	Sales/Marketing Department Staff	Hard Copy	Sales Order file, Sales/Mkt dept.

Record Type	Record Description	Minimum Retention Period	How Filed	Who maintains and manages the files	Storage Medium	Location
	Customer Documents	3 Years	By Customer	Sales/Marketing Department Staff	Hard Copy	Customer file, Sales/Mkt dept.
Design Control	Opportunity Proposals	Product Life + 5 Years	By Customer	Engineering Staff	Hard Copy or Electronic	Engineering Department Files or Company Network
	Design & Milestone Reviews/DBT minutes	Product Life + 5 Years	Engineering Control Form	Engineering Staff	Hard Copy or Electronic	Engineering Department Files or Company Network
	Design Verification & Validation reports	Product Life + 5 Years	Engineering Control Form	Engineering Staff	Hard Copy or Electronic	Engineering Department Files or Company Network
	Engineering Drawing Changes	Product Life + 5 Years	Engineering Control Form	Engineering Staff	Hard Copy or Electronic	Engineering Department Files or Company Network
Purchasing and Supplier	Purchase Orders	Current year + 5 years	By plant, by PO#	Purchasing Staff	Hard Copy	Purchasing Dept.
	Supplier Financial Evaluations (D&B)	Supplier Life + 5 Years	By Supplier	Purchasing Clerk	Hard Copy	Purchasing Central Quality File
	Pre-survey Questionnaire	Supplier Life + 5 Years	By Supplier	Purchasing Clerk	Hard Copy	Purchasing Central Quality File or QA Department
	On-site Evaluation	Supplier Life + 5 Years	By Supplier	Purchasing Clerk	Hard Copy	Purchasing Central Quality File / QA Department
	Rating Status and	Supplier Life + 5	By Supplier	Purchasing Clerk	Hard Copy	Purchasing Central Quality

Record Type	Record Description	Minimum Retention Period	How Filed	Who maintains and manages the files	Storage Medium	Location
	Corrective Action letters	Years				File / QA Department
	First Article, Corrective Action, & Discrepant Material Reports	Supplier Life + 5 Years	By Supplier	Purchasing Clerk	Hard Copy	Purchasing Central Quality File / QA Department
Maintenance	Maintenance Logs and Orders	5 Years	By Equipment	Mfg. Eng. Staff	Electronic	Company Network
Inspection and Testing	Receiving Inspection	3 Years	Searchable database	QA/QC Staff	Electronic	Company Network or QA Department Files
	In-Process Inspection	3 Years	By Product	Production Personnel	Hard Copy	Company Network or QA Department Files
	QC Final Inspection Logs	3 Years	By Date	QA/QC Staff	Hard Copy	Quality Department Files
Calibration	Calibration Reports	Life of Gauge + 1 Year	By Calibration ID #	QA/QC Staff	Hard Copy	QA Department Files or Company Network
Non-conforming Material	Discrepant Material Reports	3 Years	Searchable Database or ID #	QA/QC Staff	Electronic and Hard Copy	QA Department Files or Company Network
Corrective/ Preventive Action	Corrective Action Reports	Life of Part	Searchable Database or ID #	QA/QC Staff	Electronic and Hard Copy	QA Department Files or Company Network
	Customer Complaints	5 Years	Searchable Database or ID #	Quality Department	Electronic and Hard Copy	QA Department Files or

Record Type	Record Description	Minimum Retention Period	How Filed	Who maintains and manages the files	Storage Medium	Location
						Company Network
Internal Audit	Product Audit Reports	3 Years	Report #	Quality Systems Manager	Electronic and Hard Copy	QA Department Files or Company Network
	Quality System Audit Reports	3 Years	Report #	Quality Systems Manager	Electronic and Hard Copy	QA Department Files or Company Network
Training	Training Rosters/Records	Permanent	By Employee	Human Resources / Department Supervisors	Electronic and Hard Copy	Human Resource Employee Files or Company Network
	Qualification Assessments	Permanent	By Employee	Human Resources	Hard Copy	Human Resource Employee Files

2. Management Responsibility

2.1 Management Commitment

AMETEK STCBU has implemented a Quality Management System to support the Quality Policy and to continually improve its effectiveness in accordance with the requirements of ISO 9001 and any applicable statutory and regulatory requirements as appropriate.

2.2 Customer Focus

AMETEK STCBU is committed to assuring customer requirements and expectations are met through application of advanced technology, reliable engineering, proper application engineering, efficient manufacturing and order processing and outstanding follow-up and field support.

2.3 Quality Policy

AMETEK STCBU has established a Quality Policy to provide a framework and objectives for an effective Quality Management System relevant to our goals and the expectations of our customers.

> 1.1 Quality Policy
>
> *1.1.1 The AMETEK – Sensor Technologies team works collaboratively with our customers to continually improve our business processes, product designs and technical services to ensure customer satisfaction.*

2.4 Planning

2.4.1 Quality Objectives

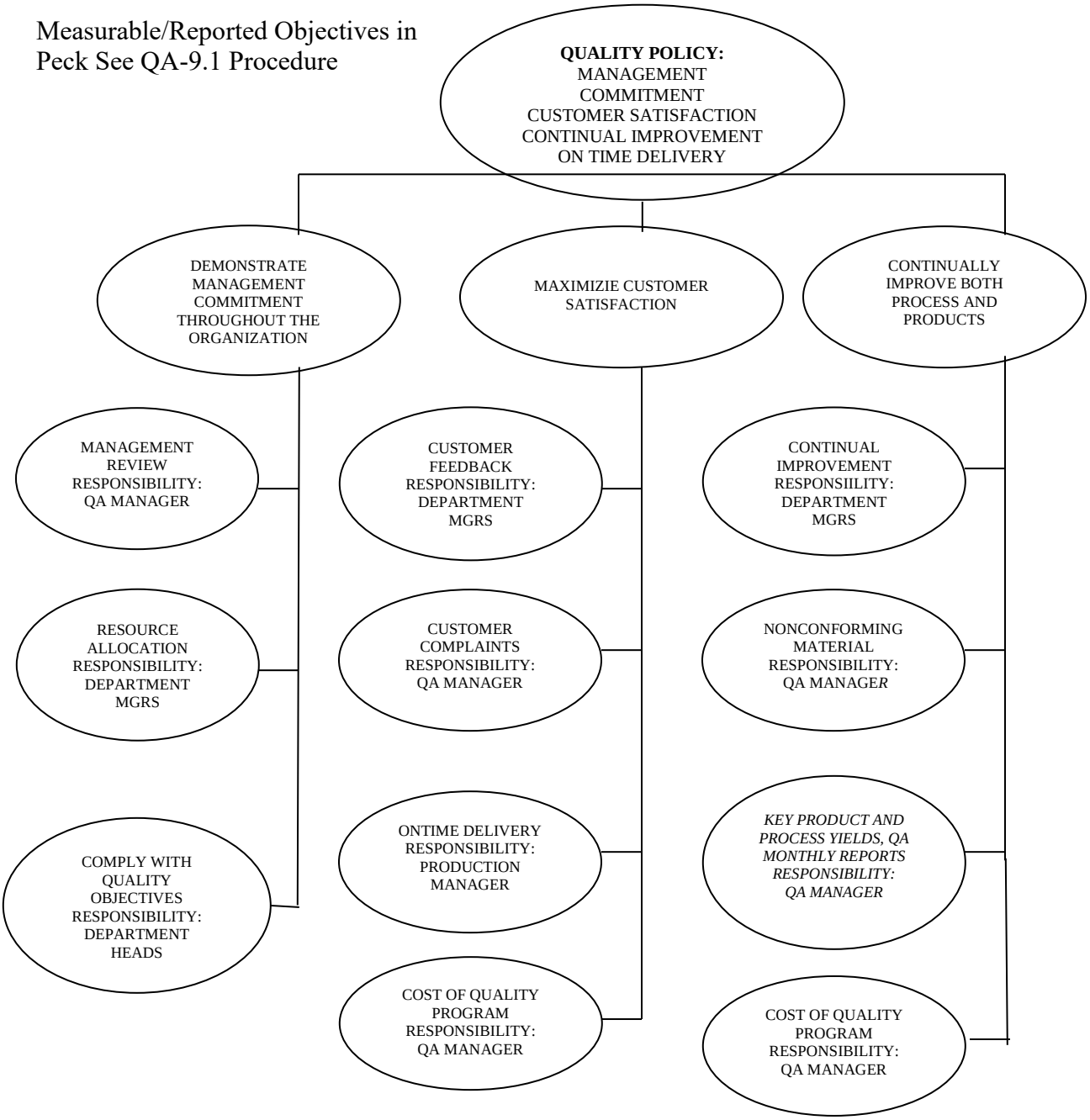
All department managers are responsible for identifying and implementing the processes, resources, and controls to achieve the required quality.

See Figure 2 for the major quality objective initiatives to support the Quality Policy and the Quality Management System.

Figure 2

Quality Objectives

Measurable/Reported Objectives in Peck See QA-9.1 Procedure



2.4.2 Quality Management System Planning

AMETEK STCBU department managers are responsible to provide the appropriate resource requirements for planning, provide adequate resources, and assign trained personnel to execute all functions of the Quality Management System.

When organization changes or changes to the quality management system are implemented or responsibilities are redefined it is the responsibility of the Human Resources department and appropriate department managers to insure the timely revision of associated documentation and the proper training of associated personnel.

2.5 Responsibility, Authority, and Communication

2.5.1 Responsibility and Authority

The AMETEK STCBU department managers are responsible for ensuring that adequate resources and trained personnel are available to carry out the work and verification activities. This will be accomplished as an integral part of Quality Management System. All personnel performing quality functions have sufficient, well-defined responsibilities, authority, and the organizational freedom to identify, evaluate and solve problems that arise. All personnel have the responsibility to stop process, which produce nonconforming material.

The organizational charts in figure 3 of this manual define organizational reporting relationships. Individual job descriptions are maintained for all personnel, which defines both the authority and qualifications associated with the job.

The Quality Assurance Department shall have the authority and responsibility to identify and record any product, process, and quality system problems or deficiencies and to prevent the recurrence of any non-conformities relating to the products and processes of the quality system.

Executive Administration

- To assign functions necessary to carry out corporate objectives. This includes responsibility for assurance that they are being carried out.
- Establish goals for the organization for each operating period.
- Review departmental operating plans for consistency with corporate goals, management philosophy, and procedures, using established techniques for problem solving and decision-making.
- Analyze AMETEK STCBU strengths and market conditions to decide what businesses we will be in.
- Decide what major improvements and extensions of our technology must be made in order to meet our long-range business goals.

- Decide how the company needs to be organized in order to achieve our long-range goals.
- Communicate above plans to others within the organization as needed

Marketing/Sales/Customer Service

- Conducts market research and analysis to establish the desired quality characteristics
- Establishes functional specifications of products and associated services
- Advertises and promotes the company's products, emphasizing their quality aspects
- Monitors the quality of competitors
- Carries out contract and order review
- Provides customer liaison and service
- Conducts research and analysis to determine current and future customer expectations
- Provides assistance to represent the needs of the customer in internal processes and functions

Engineering

- Prepares specifications from functional specifications, product briefs & customer specified requirements
- Designs products and documents the design for manufacturability
- Coordinates design reviews
- Administrates verification & testing of designs
- Documents design outputs
- Performs product support and maintenance of existent designs
- Leads advanced product quality planning
- Verifies designs and establishes design performance control points

Quality

- Establishes & maintains the quality management system
- Audits implementation of the quality system
- Initiates requests for & follows up on corrective & preventive actions
- Processes customer complaints
- Collects performance & quality data
- Assists Marketing/Sales/Customer Service in representing customer needs
- Provides input to Quality Planning process (Control/Quality Plans)
- Assure that all products conform to AMETEK STCBU published specifications and meet all applicable requirements.

Materials / Purchasing

- Responsibility to assure that our inventory is of the requisite quality, quantity and at a reasonable cost, now and in the future.
- Selects qualified suppliers
- Prepares & approves purchasing documents
- Monitors and assesses supplier performance

Operations

- Determines production personnel and equipment requirements

- Controls and monitors processes
- Defines workmanship standards in accordance with specifications.
- Maintains production equipment
- Administrates storage areas, shipping & receiving
- Provides input to Quality Planning process (Control/Quality Plans)

Human Resources

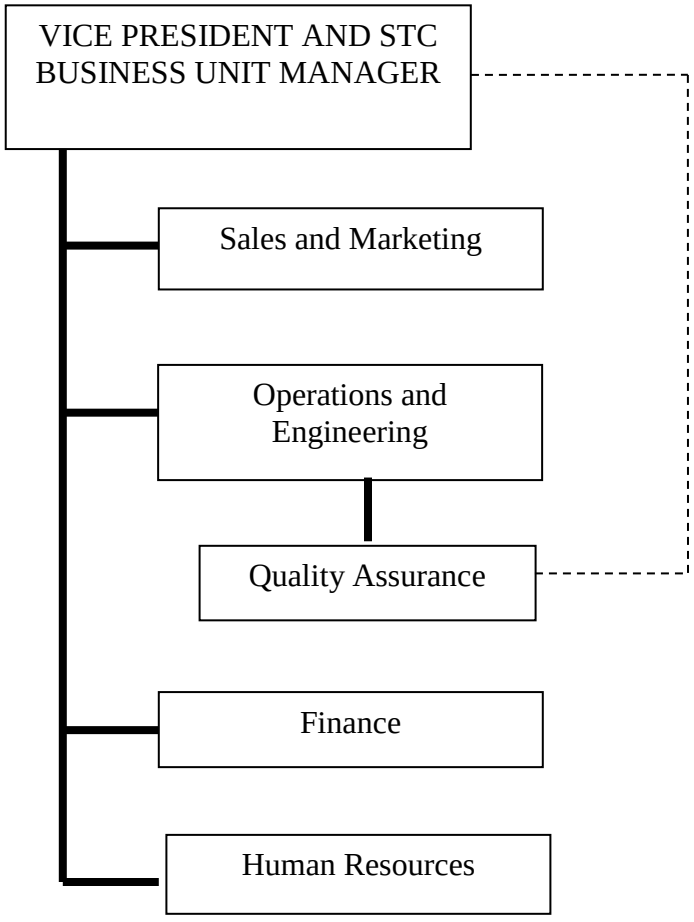
- Maintains personnel qualification requirements
- Implements measures to motivate personnel. Coordinates training

Finance

- To ensure that the company remains in a strong financial position so that growth out of earnings will be sufficient to obtain the corporations goals and objectives
- Provide accurate and timely financial reports to effectively monitor the business plan
- Continually analyze cash outlays and receipts to insure optimum cash flow
- Safeguard the organizations assets by instituting effective internal control procedures and recommending cost savings when applicable.

Figure 3

AMETEK STCBU Organization Chart



2.5.2 Management Representative

The Quality Assurance Manager is the designated Management Representative responsible to establish, implement and maintain the processes required to ensure conformance to the AMETEK STCBU Quality System Manual and to the ISO-9001 standard.

The Quality Assurance Manager has the responsibility to report to Upper Management on the performance of the Quality Management System, and the need for any improvements to the Quality System, and to promote the awareness of customer requirements throughout AMETEK STCBU.

2.5.3 Internal Communication

AMETEK STCBU Management ensures that appropriate communication means are established within the organization and that communication takes place regarding the customer's needs and the effectiveness of the quality management system. procedures, company and department training, meetings, bulletin board postings, and email are the some of the methods used to accomplish effective internal communications throughout the organization.

2.6 Management Review

2.6.1 General

The Quality Assurance Manager shall have the management responsibility for reporting on the performance of the quality system in satisfying the requirements of ISO-9001 and to review the effectiveness of AMETEK STCBU quality system, corporate quality policy, quality objectives and as a basis for improvement.

Management reviews will be conducted annually. Management reviews may be held at other times if warranted by organizational changes or changes to the quality management system.

2.6.2 Review Input

Management review input will consist of the following inputs:

a) audit results,
b) customer feedback,
c) process conformance and product conformity,

d) status of preventative and corrective action,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

2.6.3 Review Outputs

Management review outputs will contain any decisions and actions related to:

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

The quality assurance manager is responsible to issue minutes of the management review as records per section 2.4 of this manual.

3 Resource Management

3.1 Provision of Resources

Department managers are responsible to determine the appropriate resources to implement, maintain, and continually improve the effectiveness of the quality management system, to enhance customer satisfaction by meeting customer requirements.

3.2 Human Resources

3.2.1 General

Department managers in conjunction with Human Resources are responsible for insuring that all personnel performing work affecting product quality are competent, based on appropriate education, training, skills, and experience. The Human Resources Department provides guidance for training done by supervisory personnel and coordinates specialized training, which affects several departments.

3.2.2 Competence, Awareness, and Training

Department managers are responsible to provide training in the skills required for employees under their supervision to perform their job. Department managers are

responsible to evaluate the performance of employees and provide retraining when performance is unacceptable.
Effectiveness of personnel training is accomplished by yearly performance reviews, the monitoring of process performance and internal auditing.

Department managers are responsible to ensure that personnel are aware of the relevance and importance of their activities and how the contribute to the achievement of the quality objectives.

3.3 Infrastructure

AMETEK STCBU establishes and maintains the facilities, utilities, all associated hardware, software and supporting services needed to achieve product quality.
This includes:

- Maintaining the premises in a state of order, cleanliness and repair appropriate to the product and services we provide.

- Compliance with applicable standards, codes, planning documentation and documented procedures.

- Maintenance department staffed with necessary skills to support the daily operations of the plant.

3.4 Work Environment

AMETEK STCBU establishes and maintains the appropriate work environment needed to achieve product quality
This Includes:

- Lighting that is appropriate for tasks being performed. General lighting for routine activities within the building and parking lot. Special task lighting in inspection areas where close visual attention is required.

- HVAC system for employee's comfort and wellbeing.

- Rest facilities located conveniently to all areas of the plant.

- Break and lunch facilities with food and beverage vending areas.

- A first aid team available during all working hours for employee emergencies.

- An employee's social club to organize recreational activities for employees and their families, retirement, holiday and anniversary celebrations.
- An Employee Assistance Program is in place and available to all employees to assist with personal issues such as emotional, medical, legal and financial advice.

4. Product Realization

AMETEK STCBU Plans and develops the processes needed for product realization consistent with the requirements of the other processes of the quality management system.

4.1 Planning of Product Realization

In planning of product realization AMETEK STCBU shall determine the following as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes, documents, and provide resources specific to the product;
c) the required verification, validation, monitoring, and inspection activities specific to the product and the criteria for product acceptance.

The output of this planning will be documented shall be in a form suitable for AMETEK STCBU methods of operation.

4.2 Customer Related Processes

4.2.1 Determination of Requirements Related to the Product

AMETEK STCBU have the appropriate processes and procedures in place as applicable to determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer but necessary for specified or intended use, if known;
c) statutory and regulatory requirements related to the product and any additional requirements determined by AMETEK STCBU.

4.2.2 Review of Requirements Related to the Product

AMETEK STCBU reviews the requirements related with the product prior to committing with a customer to supply the product to insure that all parties have agreed that:

a) the product requirements are defined;
b) contract or order requirements differing from those previously expressed are resolved;
c) the defined requirements can be achieved.

Records of the results of the review and actions arising from the review shall be maintained in the customer order file.

When the customer provides no statement of requirements, the customer requirements are confirmed before acceptance.

When required by contract, the Customer Service Department will obtain customer approval for alternative processes, inspection methods, and tooling or equipment changes prior to implementation.

When product requirements are changed AMETEK STCBU sales department is responsible to ensure relevant documents are amended and relevant personnel are made aware of the changed requirements.

4.2.3 Customer Communication

AMETEK STCBU develops and implements effective methods of communicating with customers in relation to product information, inquires, contracts, purchase orders, including amendments, customer feedback and complaints.

4.3 Design and Development **Drexelbrook and PMT Products**.

4.3.1 Design and Development Planning

New Product Development at AMETEK Drexelbrook and PMT is broken down into three phases, which outline the plans and controls by Sales, Marketing, Engineering, and Manufacturing, to accomplish the goals and objectives of each respective phase. The three phases of new product development are Proposal Phase, Development Phase, and Batch Release Phase. (Ref. 440-0010-007) This planning includes the appropriate review, verification, and validation to each phase and the responsibilities and authorities for design and development.

4.3.2 Design and Development Inputs

Design inputs are documented in the "Product Development Proposal" (PDP). These inputs include but are not limited to:

a) functional and performance requirements;
b) applicable statutory and regulatory requirements;
c) information from previous similar designs;
d) customer or other requirements, essential for the design and development of new products.

The "Product Development Proposal" is reviewed by Engineering and Marketing for adequacy and to assure the design is complete, unambiguous, and does not conflict. Final project authorization is by the Business Unit Manager.
After the project is approved, the Project Coordinator will assemble a team with representatives from Marketing, Service, Purchasing,

Product Engineering, Manufacturing, and Quality Assurance departments.

4.3.3 Design and Development Outputs

AMETEK Drexelbrook and PMT provides the outputs in a form that enables verification against the design and development input and approved before release.

The design and development outputs will include:

- The input requirements for design and development;
- Appropriate information for purchasing, production, and service;
- Product acceptance criteria;
- Characteristics of the product that are essential for its safe and proper use.

4.3.4 Design and Development Review

Design reviews are conducted by the New Product Development Team at suitable stages throughout the design, usually scheduled at a milestone point in the project. Design reviews are typically held after completion of the first prototype but before submittal to the approval agency and before Batch Release Phase.
Additions to the development team may be included in the review if appropriate
The criteria for design reviews shall contain but are not limited to:

- Evaluate the ability of the results of design to meet requirements;

- Identify any problems and propose necessary actions.
- Records of the Design and development reviews shall be maintained.

4.3.5 Design and Development Verification

The Engineering Department has the responsibility during the development stage to verify the design to ensure the design and development outputs meet the design and development input requirements. Records of the results verification and any necessary actions shall be maintained.

4.3.6 Design and Development Validation

The Service Department in conjunction with the Engineering Department has the responsibility for validation of new production designs. Field proving sites are selected before the general release of

new designs to validate the product is capable of meeting the requirements for specified applications or intended use.

4.3.7 Control of Design and Development Changes

Changes to new products under development are the responsibility of the product development team. Changes to existing designs are governed by the engineering drawing order procedure 440-0015-003. Changes are reviewed, verified, validated as appropriate and approved before implementation. The review of changes includes the evaluation of the effect of the changes on component parts and products already delivered. Records of the results of changes and any necessary actions are maintained

4.4 Design and Development **- Hunter Spring Products (Reference procedure EN201-23)**

4.4.1 Design and Development Planning

The Project Engineer is responsible for establishing a design plan prior to commencement of any design activities. The plan divides the design process into phases: identifies design activities, assigns responsibilities for carrying specific activity, and specifies the design verification requirements. The plan also schedules design and verification activities, including design reviews. A Project Engineer, who is ultimately responsible for all aspects of the project, manages every design project. Engineering will assign a unique project identification number to each design project. All documentation related to the design project will be identified with the unique identification number and will be filled in a master file in the engineering department. Files will be kept in both hard copy and electronically.

4.4.2 Design and Development Inputs

Sales/Marketing will provide the initial input into design engineering in the form of an Opportunity Proposal. Through an iterative process between sales/marketing, design engineering and the customer or market, a Preliminary Product Proposal may be prepared. For Customer-driven projects/products, sales/marketing will notify the customer in writing of the finalized concept, product specifications, delivery schedule, and other relevant information by a Letter of Acknowledgment. This will include key documents such as an AMETEK outline for customer approval.

When required, verification test plans will be submitted to the customer for approval prior to initiating any testing. Similar previous designs will be benchmarked for such items as: field performance, customer complaints, and durability and capability indexes.

When design input and/or design output is required to be transmitted to the customer or stored in CAD/CAE systems format, the Project Engineer is responsible for ensuring that the computer systems are compatible with customer's system. If compatibility cannot be achieved, the customer will be formally notified and the situation will be resolved.

Computer software used for carrying out calculations and other design activities is qualified and approved. Standard software, purchased from commercial sources, will be ordered with validation certificates whenever possible. Software developed in-house will be validated and approved prior to release. Software documentation comprises testing specification approved by the Project Engineer and validation records demonstrating its correct functioning. Software that has been used in design for at least one year prior to implementation of this procedure and that has given satisfactory and correct performance on previous design projects may be authorized for use without validation testing. Each new revision of software is also tested, approved and identified with a release number.

Design inputs include but are not limited to:

a) functional and performance requirements;
b) applicable statutory and regulatory requirements;
c) information from previous similar designs;
d) customer or other requirements, essential for the design and development of new products.

4.4.3 Design and Development Outputs

Design process includes efforts to simplify and optimize the product and implement innovative solutions. The process also focuses on reduction of production costs and waste. The techniques used to achieve these goals are, as appropriate: Quality Function Deployment (QFD); Design for Manufacturing and Assembly (DFM/DFA); Value Engineering (VE); Design of Experiments (DOE); Failure Mode and Effect Analysis (FMEA); Cost/Performance/Risk Analysis; and use of feedback from testing, production and field experience.

Primary design output consists of documents and data that define the product and instruct how to manufacture it. These documents include drawings, specifications, procedures, required software, workmanship standards, acceptance criteria, process operator instructions and so forth. Secondary design output consists of documents supporting the design. These documents include calculations, analysis, test results, verification and validation reports and references to other documents supporting the design.

All primary design output documents are reviewed and approved prior to issue. Only the Project Engineer or a formally designated representative has the

authority to issue and release these documents. Design output documents are separated in terms of hardware and software.

a).The hardware design output is considered to be those documents generated during the design implementation phase that are subsequently transferred to procurement and production tests and inspection processes used to manufacture the product.

b).Software design output, in general, will include a set of drawings that refer to archived copies of source code and copies of the binary version of the software product. Additional supporting documents may also be required if identified in the project software plan.

Design output documentation is structured through the Master Bill of Materials to provide key information for all manufacturing processed.

The design and development outputs will include:

- The input requirements for design and development;
- Appropriate information for purchasing, production, and service;
- Product acceptance criteria;
- Characteristics of the product that are essential for its safe and proper use.

In both processes, approved drawings and product structures are required before the project is released into production.

4.4.4 Design and Development Review

Design review will be conducted at predetermined stages and schedules in the design project plan. The design review will be initiated by the project engineer but will be conducted by the Design Build Team and, as required, other specialist personnel, including the customer.

Design reviews will audit the evolving design and assess how well it meets the design input requirements. Results will be documented. Included will be such items as: actions, responsibilities, time frames and follow up verification of previous actions. The Design Review will be considered a quality record.

The criteria for design reviews shall contain but are not limited to:

- Evaluate the ability of the results of design to meet requirements;
- Identify any problems and propose necessary actions.

Records of the Design and development reviews shall be maintained.

4.4.5 Design and Development Verification

The purpose of design verification is to demonstrate that the design output meets the design input requirements, which will include a prototype program. At a minimum, the design is verified and validated by holding and recording design reviews, by prototype testing (when required), and by inspection and testing of

finished products from the production pilot run. Other forms of verification, such as carrying out alternative calculations the design with a similar proven design, may also be used when appropriate. Design verification activities are identified in the design project plan. Production processes and readiness for mass production are also verified and validated.

4.4.6 Design and Development Validation

The purpose of design validation is to demonstrate that the designed product performs satisfactorily under real or simulated conditions of intended and unintended use and are typically performed on final product. Multiple validations can be performed if there are different intended uses. As the design evolves, required design changes may be identified from preliminary studies, design reviews, prototype testing, etc. During development of the design project, proposed design changes are reviewed and authorized by the DBT. As long as the customer-defined design input is not affected, design changes implemented prior to release of the design do not need to be approved by the customer. Design verification and validation are concluded with complete layout inspection, material testing and performance testing of products that have been manufactured during the production pilot run.

4.4.7 Control of Design and Development Changes

Design changes are considered after design is released from new product development. These include changes required to correct deficiencies, improve performance or facilitate improvements to manufacturing capabilities. Major design functionality changes, which may implement unproved processes or design methodology for a given product, would be considered for new product development planning.

Change requests may circulate with “mark-up” documentation defining the purpose and scope of change. Any AMETEK Hunter Spring Products personnel at which time the review administration process begins by way of the prescribed distribution can do initiation of a revision request. Approval of the revision request form is verification of the design change review. The amount of final verification will be based on the scope of the changes. Upon approval of the change, the documentation is revised and controlled.

When a customer controlled product is involved prior to implementing the change, it will be forwarded to the customer for written approval or waiver of such approval. Design changes may not be implemented without written approval from the customer. All customer-specific product design information is kept confidential and is not released externally to anyone without written authorization of the customer.

4.5 Purchasing

4.5.1 Purchasing Process

Procurement of materials and services is limited to suppliers and sub-contractors approved for specific items or services.

Suppliers and sub-contractors are evaluated for producing materials and assemblies or providing services to specified requirements.

Suppliers and sub-contractors are evaluated using the following methods on-site survey, capability survey, inspection history, or sample submission depending upon the effect of the purchased material on the final product. Reference P100 Series Purchasing procedures

Where required by contract customers will have the right of access to the facility and the facilities of any supplier.

Where required by contract AMETEK PMT AND HUNTER SPRING will apply for customer approval for alternative process, inspection methods and inspection tooling and equipment prior to implementation.

Purchase orders issued to suppliers contain the specific requirements for the items to be provided. Records of approved suppliers and sub-contractors are maintained.

4.5.2 Purchasing Information

AMETEK STCBU Purchasing department insures that specified purchase requirements are adequate prior to being communicated to the supplier including where appropriate:

a) requirements for approval of product, procedures, processes and equipment;
b) qualification of personnel and quality system requirements.

4.5.3 Verification of Purchased Product

Verification of purchased products is the responsibility of the Receiving Inspection Department to ensure purchased product meets specified purchase requirements.

All controlled parts and materials that affect or become part of the final product shall be subject to verification upon receipt to assure conformance to technical requirements. Such verification shall include visual, dimensional inspection, or test, or other methods as required affirming material acceptability.

Material and products waiting testing will be segregated from approved stock. Non-conforming material will be segregated and controlled.
Supplier material certifications and test reports used for verification shall be maintained on file.

Receiving inspection may be adjusted upon the basis of the quality assurance program exercised by suppliers. Historical evidence of the suppliers' satisfactory control of quality may be used to adjust the amount and kind of receiving inspection.

Purchased product that is to be inspected or verified at the supplier's facility requires special arrangements from AMETEK STCBU purchasing department.

4.6 Production and Service Provision

4.6.1 Control of Production and Service Provision

AMETEK STCBU Department Managers, under controlled conditions, establish and maintain production and services specific to their department's responsibilities. This includes the availability of information that describes the characteristics of the product, necessary training and work instructions, use of suitable equipment, the use of monitoring and measuring devices, and the implementation of release, delivery and post-delivery activities.

Customer orders are reviewed by the Customer Service Department prior to release to manufacturing to assure the requirements to produce product are obtainable in the terms of the contract and the materials and resource availability to schedule the orders to satisfy the customer need dates.

The Production Department is responsible for planning, generating, and scheduling work orders to the Manufacturing Department to provide routing instructions and work orders.

In addition to work orders and routing instructions, engineering design drawings, specifications, assembly procedures, and travelers are key documents for control of production and service.

The manufacturing department is responsible for maintaining process equipment to ensure continuing process capability.

4.6.2 Validation of Processes for Production and Service Provision

Processes for production and services shall be validated where subsequent monitoring or measurement cannot verify the resulting output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

AMETEK STCBU Engineering, Purchasing, Manufacturing, and Quality Assurance Departments establish arrangements for these processes including:

a) defined criteria for review and approval of the process
b) Approval of the equipment and qualification of personnel
c) Use of specific methods, procedures, and standards.
d) Requirements for procedures
e) Revalidation

Where required by contract, a First Article Inspection to inspect, verify and record the results of an item from the first production run of a new part / assembly and following any change that invalidates the previous results.

4.6.3 Identification and Traceability

Identification

Materials and product are identified throughout production where appropriate. This identification can consist of various methods including AMETEK STCBU part numbers, model numbers, customer order numbers, serial numbers, material size, color codes, shop orders, travelers and routers.

Product shall be identified with respect to monitoring and measuring requirements where appropriate. Various methods used for product status identification include inspection stamps, inspection stickers, inspection reports, and forms, hold point areas and rejection and acceptance tags.

Scrap material will be identified to prevent it from inadvertent use.

Traceability

The Customer Service Department maintains the following information for customer orders.

- Customer Purchase Order Number
- AMETEK STCBU Order Number
- Equipment Model / Part Numbers
- Equipment Serial Numbers
- Customer Address
- Shipment Date and Quantity

The traceability trail is linked to equipment model numbers, serial numbers, and shipment date. The shipment date can be associated to a production time window derived from various production records, such as, material receipt date and revision date records. Equipment model numbers can be linked to serial numbers, which are linked to AMETEK STCBU order numbers.
Mill Certification Traceability only when required by customer order or customer contract.

4.6.4 Customer Property

Customer returned goods will be handled in accordance with the QA212 Series Procedures.

Customer property will be inspected to determine the quantity received the condition of the property and correctness of the accompanying paperwork.

Customer property will be identified and stored in a protected area to minimize the possibility of damage and/or deterioration.

Customer property is not altered in any form without prior approval from the party supplying the property.

Any customer property lost, damaged, or otherwise found to be unsuitable for use shall be reported to the customer and records maintained in the order folder.

4.6.5 Preservation of Product

Handling

All materials shall be properly handled in such a manner as to prevent damage, contamination, and or deterioration.
Specific handling procedures shall be developed for materials and products as required.

Storage

All materials shall be stored in such a manner as to prevent damage, contamination, and or deterioration.

All items in stock shall be identified by AMETEK STCBU part number.

All age-controlled items shall be identified and controlled by part number and date.

All end items shall be stored in a controlled area prior to shipping to prevent damage, misuse, etc.

Protection

All product and material to be used as product shall be maintained in a manner to assure proper preservation and segregation where appropriate.

Packaging

All packaging will be in accordance with specific procedures developed for specific products to ensure all equipment arrives at the customer location complete and free of damage .
Special packaging or marking requirements when specified by contract or purchase order shall be the responsibility of the Shipping Supervisor.

4.7 Control of Monitoring and Measuring Devices

AMETEK STCBU Quality Assurance Department is responsible for determining the monitoring and measurement requirements and establishes, implements, and maintains procedures to control, calibrate and maintain inspection, measurement, and test equipment used to demonstrate the conformance of product to the specified requirements.

Where necessary to ensure valid results, measuring equipment will:

a) be calibrated or verified at specified intervals, prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) be adjusted or readjusted as necessary;
c) be clearly marked with calibration status;
d) be safeguarded from adjustment that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance, and storage.

AMETEK STCBU Quality Assurance department implements and maintains calibration systems to insure adequate control of inspection, measuring and test equipment and to assess the validity of previous results when the equipment is found not to conform to requirements. Calibration records are maintained for each item of inspection, measuring, and test equipment to provide a documented calibration history.

When computer software is used in monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed prior to initial use and reconfirmed as necessary.

5 Measurement, Analysis, and Improvement

5.1 General

AMETEK STCBU shall determine the planning and implementation methods for monitoring, measurement, analysis, and improvement process needed:

a) to demonstrate conformity of the product,
b) insure conformity to the Quality Management System, and

c) to continually improve the effectiveness of the Quality Management System.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

Customer feedback and satisfaction is crucial to AMETEK STCBU future success and is the basis and focus of the Quality Policy and the Quality Management System.

AMETEK STCBU management team views all customer feedback including customer complaints, warranty returns, design recommendations, or suggestions for improvement as an opportunity to continually improve the products and services we provide to our customers.
Customer complaints are forwarded to the Quality Manager and are reviewed to assure that the customer has been satisfied and appropriate actions are taken to prevent recurrence.

Customer suggestions for improvements are forwarded to the appropriate department or product manager, or the new product development teams.

A database is maintained on the AMETEK STCBU network of all Customer complaints.

5.2.2 Internal Audits

Internal Audits shall be conducted on all elements of the quality system to verify the effectiveness of AMETEK STCBU Quality Management System and the requirements of ISO 9001.

The Quality Assurance Department will prepare an audit schedule to define the system audits scheduled for each calendar year assuring all elements of the quality system are covered.

Elements of the Quality System where problems are known or suspect can be audited on a more frequent basis as determined by the Quality Assurance Manager.

The internal audits will be conducted mainly by Quality Assurance personnel with additional members from Engineering and Manufacturing or other departments as required.

All personnel performing Quality System Audits shall be trained and records of training will be retained.

The audit team members assigned to audit an area shall be independent of those having direct responsibility for the audited area and to ensure the auditors do not audit their own work.

The results of the audit shall be recorded on the audit plan describing all the findings. The audit report will then be distributed to the Department Head of the audited area, the area supervisor, along with copies to the Business Unit Manager and any affected individuals or departments.

Records of audits and follow-up actions shall be maintained.

5.2.3 Monitoring and Measurement of Processes

The Quality Assurance Department has the primary responsibility to apply suitable methods monitoring and, where applicable measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate to ensure conformity of the product.

Monthly or quarterly status reports is the primary method used to effectively monitor and measure AMETEK STCBU key quality management system processes. These status reports monitor and measure: key product and process yields, customer complaints, sales order accuracy, key supplier performance and delivery performance.

5.2.4 Monitoring and Measurement of Product

AMETEK STCBU Manufacturing Department has the primary responsibility implement and maintain comprehensive methods for monitoring and measuring the characteristics of the product to verify that product requirements have been met at appropriate stages of the product realization.
Evidence of conformity with the acceptance criteria shall be maintained and records shall indicate the person(s) authorizing the release of product.
Product release and delivery is dependent upon compliance with appropriate requirements and procedures.

The primary method to accomplish product monitoring and measurement is the use of documented travelers, and inspection and test procedures.

All assemblies or products that require in-process inspections or tests shall be identified by specific procedure or hold points identified in drawings, procedures, or routing instructions.

Various methods are used to record the results of acceptance including documented forms, logs, test data sheets, and the use of inspection stamps.

AMETEK STCBU recognizes that the customer has the right to inspect their products at AMETEK STCBU or at a subcontractor's facility, if specified in the contract or purchase order. AMETEK STCBU will make available personnel, and inspection equipment as required.

5.3 Control of Nonconforming Product

Product or material to be used in product, which does not conform to the product requirements, is identified and controlled to prevent its unintended use or delivery.

Nonconforming material is identified as nonconforming and segregated for disposition. Reworked nonconforming product or material will be re-inspected to assure conformance to requirements.

Nonconforming materials parts or products are reviewed in accordance with procedures and may be accepted under concession by authorized personnel and where applicable the customer, provided all regulatory requirements are met.
When nonconforming product or material has been detected after delivery or use, the Quality Assurance Department has the responsibility to determine, the actions required appropriate to the effects or potential effects of the nonconformity.

5.4 Analysis of Data

AMETEK STCBU Quality Assurance Department has the responsibility to determine, collect and analyze the appropriate data to demonstrate the suitability and effectiveness of the Quality Management System.

Methods used to generate relevant data are reviewed periodically to ensure the information provided relates to:

a) customer satisfaction,
b) conformity to product requirements,
c) characteristics and trends of process and products including opportunities for preventive action.
d) key supplier performance.

5.5 Improvement

5.5.1 Continual Improvement

AMETEK STCBU is committed to continually improve the effectiveness of the Quality Management System through utilizing the quality policy, quality objectives, audit results, analysis of data, warranty returns, corrective and preventative actions and management reviews.

5.5.2 Corrective Action

AMETEK STCBU Quality Assurance Department establishes implements and maintains the procedures to ensure corrective action to eliminate the cause of nonconformities in order to prevent recurrence and ascertain that the actions taken shall be appropriate to the effects of the nonconformities encountered.

The corrective action procedures shall define the requirements for:

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing the action needed,
e) record the results of action taken and,
f) reviewing corrective action taken.

The need for corrective action is identified through data from these primary sources.

- Production yield reports,
- Nonconforming product inspection reports,
- Internal audits,
- Customer feedback or complaints,
- Supplier performance.

5.5.3 Preventative Action

AMETEK STCBU Quality Assurance Department establishes implements and maintains the procedures to ensure corrective action to eliminate the cause of potential nonconformities in order to prevent recurrence and ascertain that the actions taken shall be appropriate to the effects of the potential nonconformities encountered.

The preventative action procedures shall define the requirements for:

a) determining potential nonconformities and their causes,
b) determining the need for action to prevent occurrence causes of nonconformities,
c) determining and implementing the action needed,
d) record the results of action taken and,
e) reviewing preventative action taken.

The need for preventative action is identified through data from these primary sources:

- Production yield reports
- Inspection and Test Records

- Audit Observations
- Field Service Reports
- Customer Feedback or Complaints
- Sub-Contractor Problems
- Observations and Reports from Personnel

Appendix A: Partial list of Quality System Procedures

Proc Ref	Procedure Title	Pennsylvania Procedure No.	Michigan Procedure No.
1	Engineering Drawing Control Drexelbrook, PMT, Products	440-0015-003	N/A Controlled in Pennsylvania
2	Engineering Drawing Control Hunter Products	EN201-22	N/A Controlled in Pennsylvania
3	Manufacturing Document Control	440-0017-750	MFG-EN 7.5.3-13 MFG 8.5.2, MFG-8.1 and MFG 8.5.1 Peck
4	Control of Records	440-0018-435	QA - 7.5.3 Peck
5	Corrective Action	440-0018-430	QA-10.2 Peck
6	Control of Nonconforming Material	QA211-1	EN-8.7, MFG-8.7-1 and MFG-8.7-2 Peck
7	New Product Development PMT Products	440-0010-007	N/A Controlled in Pennsylvania
8	New Product Development Hunter Products	EN201-23	N/A Controlled in Pennsylvania
9	QMS Internal Audits	440-0018-155	QA-9.2 Peck
10	Control of Measuring and Test Equipment	440-0018-186	QA-7.1.5 Peck
11	Quality Policy	440-0018-421	QA201-2
12	Purchasing and Supplier Approval	P100 Series	Pur-8.4-2 Peck
13	Receiving Inspection Procedure	440-0016-022	QA-8.6-6 Peck
14	Sampling Procedure	440-0018-276	Pur-8.6-3 Peck
15	Hunter Spring Inspection Procedure Product Performance Inspection	QA209-3	MFG-8.6-1 Peck