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ISSUE	EDO NO	APPD	DATE
24	12-20-113	SGA	12-16-20
25	1-24-101	SGA	01-03-24

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,

Horsham PA, 19044

And
6380 Brockway Rd
Peck Mi 48466

Scope

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. No exclusions to any of the requirements of ISO 9001 are claimed.

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: 4-24-2018

Division Vice President & Business Unit Manager
Joel Frie

Approved Date: 4-24-2018

QA Manager PA Location

Approved Date: 4-24-2018

QA Manager MI Location

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
22	2/18	SGA	Update Appendix A to include 440-0018-551 ATEX/IECEx Supplementary QMS Requirements. Update records section to refer to 440-0018-551 for ATEX/INMETRO/IECEX records retention. Add effectivity of the QMS with respect to hazardous location products to section Sec2.6.2.h
23	4/18	SGA	Reformat and update to meet requirements of ISO-9001:2015
24	12/20	SGA	Add requirement for Customer Notice of Change
25	1/2024	SGA	Update Appendix A to include procedures to comply with CSA N299.3 Quality Assurance Program Requirements For The Supply Of Items And Services For Nuclear Power Plants, Category 3

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1. CONTEXT OF THE ORGANIZATION

1.1. UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

AMETEK STC BUSINESS UNIT HORSHAM, PA has determined the following external and internal issues to be relevant to its purpose and its strategic direction. These issues have an effect on its ability to achieve the intended results of its quality system:

External Issues

- Customer satisfaction (products with desired features, functioning properly, reliable, available in a timely manner and at a fair cost)
- Safety of products and services supplied to customers
- Environmental impact
- National and international regulatory requirements
- Competition and market share
- Investor satisfaction
- Supplier quality, cost, delivery timeliness, and uninterrupted ability to supply
- Diversity of the customer base
- Global economic climate

Internal Issues

- Employee satisfaction
- Health and safety
- Resource constraints
- Workforce knowledge and skill
- Quality of products and services
- Timely delivery of products and services
- Equipment and tools
- Speed of new product development

Information about these external and internal issues are monitored and reviewed by AMETEK STC through various means.

Information on external issues of customer satisfaction and safety of products/services are monitored by means of customer contact by the sales force, and customer feedback. Environmental impact is addressed in the Environmental, Health, and Safety program and compliance to various local, state, federal, and international environmental regulations evidenced through various permits, audits, and assessments conducted by relevant authorities. National and international regulatory requirements are considered in design and engineering activities, and compliance is monitored through various processes leading up to order fulfillment. Competition and market share are monitored through direct contact with customers by the sales and marketing functions, periodic marketing surveys, benchmarking data, etc. Investor satisfaction is monitored and managed through the AMETEK corporate executive office. The Horsham facility quality management system plays a part in overall investor satisfaction, and in turn is monitored by the AMETEK corporate executive office for the achievement of identified goals and objectives. Supplier issues relating to quality, material costs, and delivery timeliness are monitored through data obtained from activities such as receiving, incoming inspection, production issues related to procured material, periodic

evaluation of costing, and other procurement related activities. Due consideration is given to the health of supplier businesses, disaster contingency plans, and available sources of supply to ensure uninterrupted delivery of products and services for order fulfillment. Diversification of the customer base is a business management function monitored by the Business Unit Manager with appropriate input from sales and marketing with consideration given to the global economic climate through reported economic data, economic trends, etc.

Information on internal issues related to employee satisfaction are monitored through the employee performance appraisal process, employee communication meetings, an employee activities committee, and feedback to an on-site Human Resources Manager. Health and safety is executed through a formal program designed to meet local, state, and federal laws governing health and safety in the workplace and is monitored through direct involvement of management, a formal health and safety committee, local auditing, and corporate audits. Order fulfillment as a function of resource constraints is evaluated and monitored by management through the production planning process. Cross-training of employees to allow flexibility along with properly trained temporary employees are used as methods for alleviating resource constraints. As part of the process for monitoring resource constraints, work force knowledge and skills are reviewed. Appropriate training is given or contracted to ensure employees have the proper skill sets including back-up employees for order fulfillment. The quality of products and services are monitored through various in- process and final inspection and testing activities implemented to ensure products and services conform to requirements. Additional feedback from Customers on product conformance aid in monitoring the quality of products and services. Timely delivery of products and services are monitored through promised shipment dates and promised service dates conveyed to customers during the ordering process. Customers are kept informed of unforeseen events which impact these promise dates. AMETEK STC is committed to providing its work force with appropriate equipment and tools necessary to properly produce and service its products along with the necessary infrastructure. Appropriations for equipment and tooling expenses and capital are made through monitoring of the order fulfillment process to ensure the equipment and tools used are upgraded to new technologies to ensure efficiency in order fulfillment. AMETEK STC is committed to providing new products and services to its customers in a timely manner. Market surveys and direct communication with the customer base along with competitor product analysis are used to determine customer needs and features desired in the types of products and services offered by AMETEK STC.

External and internal issues are reviewed in the periodic quality management system reviews.

1.2. UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Due to their effect or potential effect on AMETEK STC Horsham facility's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, relevant interested parties are identified as follows:

Customers
Investors
Employees
Suppliers
Neighborhood bordering the facility
Community

Customers require durable products that meet their specification fit for their intended use delivered on time at a reasonable cost. These products should be safe to use and meet all regulatory/statutory requirements, so they can be used upon delivery.
Investors are looking for a higher rate of return on their money than offered through more traditional bank investment products, continued growth, and low risk on their investment. AMETEK STC employees require employment that offers job security, a good wage with good benefits, and career growth opportunities. Suppliers require timely payment for the products and services they supply along with commitment of continued business to maintain the health of their business and to meet their employees' needs. The neighborhood bordering the facility is looking for AMETEK STC to be a good neighbor operating safely not posing any danger to the neighborhood. The community at large in which the facility operates requires AMETEK STC to meet all local, state, and federal ordinances, as well as providing community funding through local taxation and donations of time, talent, and money.

1.3. DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

The scope of the AMETEK STC Horsham facility quality management system was determined considering the identified external and internal issues, the requirements of relevant interested parties, and the products and services available to customers.

The scope is defined as the design, manufacture and service of Electronic Level, Pressure Measuring and Analytical Equipment, Specialty and Constant Force Springs, Mechanical, Electrical and Data Retractable Reels for various process industries.

1.4. QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

AMETEK STC maintains an established and documented quality management system and strives to continually improve the effectiveness of the system. As part of the quality management system, the company:

- identifies the processes needed for the system and their application throughout
- determines the sequence and interaction of these processes
- determines the criteria and methods needed to ensure that both the operation and control of these processes are effective
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes
- establishes the responsibilities and authorities for these processes
- monitors, measures and analyzes these processes
- determines and addresses the risks and opportunities facing the organization in addressing the needs and expectations of its interested parties
- implements actions necessary to achieve planned results and continual improvement of these processes

The identification of necessary processes, sequences, interactions, and methods is accomplished through process flow diagrams, work instructions, computer generated routings, and other suitable documentation. The documentation adequately defines process and product characteristics necessary for adequate control and assurance of conformance to requirements. Monitoring of process parameters is performed to ensure controlled processes capable of providing consistent results of conforming product. Inspection and testing of products to defined requirements is accomplished by production operators and quality assurance personnel to assure customer requirements are satisfied

through the measurement of predetermined satisfaction indicators.

Processes affecting product conformity with requirements which are outsourced are adequately controlled, and the type and extent of control is defined in the quality management system.

2. LEADERSHIP

2.1. LEADERSHIP AND COMMITMENT

2.1.1. General

The executive management of AMETEK STC is committed to the development and implementation of the quality management system and continuous quality improvement. The executive management employs risk- based thinking in determining what areas of the business receive appropriate focus for process improvement which will lead to increased customer satisfaction. The importance of meeting customer as well as statutory and regulatory requirements is communicated to all employees by the executive management through training, department meetings and periodic employee communication meetings.

There is an established quality policy which is fully supported by all levels of management. Quality objectives are established, documented, and monitored as part of the Operational Excellence program at the company.

Management reviews are periodically conducted. As part of this review, the availability of adequate resources to accomplish the quality objectives is covered as part of the agenda.

2.1.2. Customer Focus

AMETEK STC as a manufacturing business is focused on meeting customer requirements with the aim of continuously enhancing customer satisfaction in its products and services.

Customer and applicable statutory and regulatory requirements are determined through customer communication, review of markets served, review of statutory and regulatory requirements in the markets in which products and services are delivered, involvement in industry action groups and standards committees, and in various other ways. Risks and opportunities that can affect conformity of products and services to customer requirements and statutory and regulatory requirements are determined and proactively addressed to enhance customer satisfaction.

2.2. POLICY

2.2.1. Establishing the Quality Policy

The Quality Policy at AMETEK MCT is reviewed periodically to ensure its suitability to current conditions, and is as follows:

> ***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.***

2.2.2. Communicating the Quality Policy

The quality policy is communicated to all employees in the employee handbook, and through posting of the policy in conspicuous locations throughout the facility as well as through new hire indoctrination training. It is maintained in this controlled quality assurance manual. It is also available to relevant interested parties upon request.

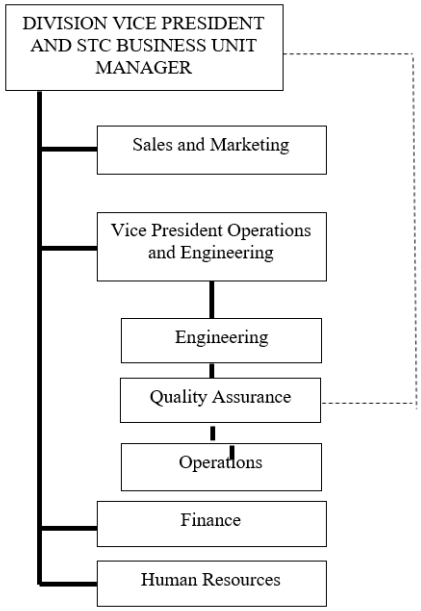
2.3. ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

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 processes, which produce nonconforming material.

The organizational charts in figure 1 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. The Quality Assurance Department shall have the authority and responsibility to ensure that the integrity of the quality Management system is maintained when changes to the quality management system are planned and implemented.

Figure 1



- ***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 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.

3. PLANNING

3.1. ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

3.1.1. Identification of Risks and Opportunities

3.1.1.1. The executive management of AMETEK STC considers the requirements and expectations of the interested parties identified in section 1.2, and the issues defined in section 1.1 that can influence the organization's ability to achieve the requirements and expectations of these interested parties.

Risks are determined starting with a top down review of each product/product line and each service offered to a customer in the context of meeting their needs and requirements for the product. Product specifications are developed for each product based on initial customer input during the product development phase and maintained throughout the product lifecycle through continued solicited customer input, market feedback, uncovered product issues, statutory laws and regulatory laws. The processes put into place to produce these products meeting or exceeding their specifications and provide these services as well as all other

supporting processes from ordering these products/services to order fulfillment and after sales servicing of these products are reviewed for potential failure modes and in turn, potential controls which can be implemented to prevent or mitigate undesired effects.

Opportunities are determined in a similar manner starting with the product/product line or service offered to customers. Input from customers and markets as to desired product features or services is solicited during the new product development process. Design reviews are conducted that take into consideration modern materials, manufacturing processes, tooling, etc. which may enhance product functionality, reduce costs, reduce delivery times, increase product reliability, or achieve other desirable effects increasing satisfaction of the relevant interested parties through better products and services, lower costs, growth of the business, etc. Data from the monitoring of customer surveys and sales/marketing feedback processes, customer complaint processes, manufacturing processes, etc. also drive improvements by incorporating customer feedback suggestions into the quality management system or addressing and correcting issues with the quality management system.

Various tools are used in the quality system to identify the risks and opportunities. For the identification of risks, tools such as brainstorming, Failure Modes Effects Analysis (FMEA), Customer and Supplier Feedback, Risk matrixes, Pareto Analysis, Trend Analysis, and Cause and effect analysis are used. For the identification of opportunities these tools are also used along with customer satisfaction surveys, market surveys, and Value Added/Value Engineering techniques.

3.1.2. Actions to Address Identified Risks and Opportunities

3.1.2.1. The actions taken to address the identified risks will include design changes to address potential failure modes using design FMEAs to reduce or eliminate identified failure modes; a formal Production Part Approval Process (PPAP) for the qualification of new parts or new sources of supply for parts; production control plans to mitigate risk in the manufacturing processes of the product which include established test and inspection points; root cause analysis of production failures, business system failures, and customer complaint trends warranting such analysis; bow-tie diagrams to analyze risks in processes, consequences, and subsequent controls; and various other actions aimed at eliminating or mitigating risks. The executive management may also decide to accept an identified risk after careful review of the risk and its consequences.

3.1.2.2. Actions taken to address opportunities will include product design changes to incorporate new features sought by customers through customer/market feedback and improvement of product functionality, reliability, and service life; development of new products and services to enter new markets and grow existing markets; supplier partnerships, Kanban agreements, and consigned inventory agreements to drive higher quality lower cost materials with quicker availability to improve order fulfillment times; value engineering activities to reduce costs of products; Kaizen events, lean manufacturing techniques, and other process improvement activities

aimed at streamlining processes and improving process outputs with respect to time, quality, and efficiency; and various other actions aimed at taking advantage of opportunities for improvement.

3.1.3. Evaluation of the Effectiveness of Actions Taken

3.1.3.1. The effectiveness of actions taken to address risks and opportunities will primarily be evaluated through the quality management review which includes a review of quality objectives and measures of meeting these objectives. The executive management will also evaluate the business through periodic financial reviews of the business.

3.2. QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

3.2.1. Overall quality objectives are established through the “Operational Excellence” and program at AMETEK STC. These objectives are measurable and encompass customer satisfaction indices, results of internal measurement and monitoring, results of supplier quality monitoring, quality costs, etc.

Supporting objectives at relevant functions and levels within the organization are flowed down through the goal setting process as part of the employee development effort.

3.2.2. The requirements for quality are defined and documented. The following activities are given consideration as appropriate, in meeting the specified requirements for products, projects and contracts.

- The preparation of quality plans.
- The identification and acquisition of any controls, process, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality.
- Ensuring the design, the production process, installation, servicing, inspection and test procedures and applicable documentation.
- Quality control, inspection and testing techniques, including the development of new instrumentation are updated as necessary.
- Measurement requirements involving capability that exceeds the known state of the art are identified in sufficient time for the needed capability to be developed.
- Suitable verification at appropriate stages in the product realization are identified.
- Standards of acceptability for all features and requirements including those which contain a subjective element are clarified.
- Quality records are identified and prepared.

The range and degree of documentation required for procedures that form part of the quality system shall be dependent upon the methods used, skills needed, and the training acquired by personnel involved in carrying out the activity.

3.3. PLANNING OF CHANGES

The quality management system is made up of inter-related processes each with inputs and intended outputs. There are times when established processes need to be changed in response to changing requirements, organizational needs, process improvements, etc. AMETEK MCT employs processes which are described in documentation such as policy manuals, standard operating procedures, work instructions, shop routers, and software programs/databases providing process instructions. When a change to a process needs to occur, a formal change management system approach is utilized which includes the purpose of the change(s) and their potential consequences submitted for review and approval by defined management or their authorized delegates. The management or delegates authorized to approve changes take into consideration the availability of resources to make the change(s), allocation or reallocation or responsibilities and authorities to support the change(s), and the effects of the change(s) on the quality management system in maintaining its integrity and ability to produce desired results. This is accomplished through the Engineering Change Process and Document Change Process employed by AMETEK MCT.

4. SUPPORT

4.1. RESOURCES

4.1.1. General

AMETEK MCT provides sufficient resources to implement and maintain the quality management system, to continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements. The executive management periodically reviews the adequacy of resources with respect to manpower, equipment, facilities, etc. to determine suitability to meeting quality requirements.

4.1.2. People

All personnel engaged in work affecting product quality have appropriate education, training, skills and experience.

The management of AMETEK STC believes that all personnel performing work affecting product quality shall be qualified to perform the work. Each manager is responsible to ensure their personnel are qualified to AMETEK STC requirements and/or certified to applicable industry or regulatory requirements. Competence is primarily evaluated through annual, comprehensive employee performance appraisals, and is a function of internal quality measures, and customer satisfaction measures.

4.1.2.1. New employee orientation training is provided to new employees including organizational policies and objectives. Periodic refresher training is also provided to employees.

4.1.2.2. Documented job descriptions and procedures are established and maintained to identify training needs. Documented procedures, internal training courses, external training, etc. are used to provide training to those personnel performing activities affecting quality.

4.1.2.3. The qualifications of personnel performing specific tasks are based on education, training and/or experience and are documented.

4.1.3. Infrastructure

A clean, safe, modern, well maintained, environmentally controlled facility is utilized in the production and servicing of products. Appropriate steps are taken to prevent cross contamination in the production and servicing processes. Calibration labs and areas are environmentally controlled to minimize the environmental effects on calibration. Ample workspaces and equipment are provided for personnel in support functions outside of production which impact product quality and customer satisfaction. All necessary utilities are provided for the proper processing and servicing activities underway. Process equipment receives scheduled preventive maintenance on a routine basis which is documented by the employees performing the maintenance. Personnel engaged in the operation or maintenance of process equipment are adequately trained, and the training documented. Process equipment is reviewed for adequacy and capability, and updates or replacement or process equipment is planned for.

Communication services are in place for telephone, fax, e-mail, and cellular communications. AMETEK STC maintains a modern computer network consisting of servers, workstations, printers, scanners, and other ancillary equipment along with associated software at the facility. The facility network is linked to other AMETEK facilities around the world, AMETEK corporate headquarters, and the internet for global capabilities. AMETEK STC maintains several internet web sites in addition to the corporate web site where customers may obtain information about the company, its products and services. A company intranet is maintained to facilitate information exchange within the company location.

4.1.4. Environment for the Operation of Processes

The proper work environment needed to achieve conformity to product requirements is determined by the management team and implemented. All relevant environmental, health, and safety standards and regulations are strictly adhered to.

4.1.5. Monitoring and Measuring Resources

4.1.5.1. General

Documented procedures will be established and maintained to control, calibrate and maintain monitoring and measuring equipment (including test software) used to demonstrate the conformance of the product to the specified requirements.

Monitoring and measuring equipment shall be used in a manner which ensures that the measurement uncertainty is known and consistent with the required measurement capability.

Software and hardware equipment will be rechecked at prescribed intervals.

Technical data pertaining to the measuring equipment will be made available for verification when required by the customer.

4.1.5.2. Measurement Traceability

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or 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 is recorded
- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage.

When measuring equipment is found not to conform to requirements, the validity of previous measuring results is assessed. The equipment is marked as nonconforming, taken out of service, and segregated. An assessment is made as to the effect on product accepted using the equipment and appropriate actions are taken which may include customer notification and recall of product.

4.1.6. Organizational Knowledge

All personnel engaged in work affecting product quality have appropriate education, training, skills and experience. The knowledge and skills necessary for each position are defined by management. A formal training program exists to ensure personnel in each position receives training identified to obtain the knowledge and skills for that position as required through internal or external means.

4.1.6.1. Internal knowledge is captured and maintained in documentation pertaining to the management system and processes that make up the management system. Personnel undergo training to this documentation and when changes to this documentation are made. External sources for obtaining organization knowledge are also utilized when internal sources are not available and to ensure current best practices.

4.2. COMPETENCE

The management of AMETEK STC believes that all personnel performing work affecting product quality shall be qualified to perform the work. Each manager is responsible to ensure

their personnel are qualified to AMETEK MCT requirements and/or certified to applicable industry or regulatory requirements. Competence is primarily evaluated through annual, comprehensive employee performance appraisals, and is a function of internal quality measures, and customer satisfaction measures.

4.2.1.1. New employee orientation training is provided to new employees including organizational policies and objectives. Periodic refresher training is also provided to employees as appropriate.

4.2.1.2. Documented job descriptions and procedures are established and maintained to identify training needs. Documented procedures, internal training courses, external training, etc. are used to provide training to those personnel performing activities affecting quality.

4.2.1.3. The qualifications of personnel performing specific tasks are based on education, training and/or experience and are documented.

4.3. AWARENESS

Personnel are made aware of the quality management system from the time they start their employment with the company throughout their time working for the company.
This includes both permanent and temporary employees. This awareness is brought about by new hire training and quality system training conducted for their assignments. The organization's quality policy and quality objectives are communicated to these employees in training and re-enforced through communication meetings. The organization's quality policy is posted throughout the organization along with key quality metrics supporting the quality objectives. As part of this awareness effort, personnel are made aware of their contribution to the quality management system, the benefits associated with conforming with the quality management system, and the implications to the company and its employees with non-conformance to the quality management system.

4.4. COMMUNICATION

Internal Communication:

The executive management ensures that appropriate internal communication concerning the effectiveness of the quality management system takes place through established communication processes and forums. These include but are not limited to:

- employee communication meetings
- monthly bulletin board postings of quality results
- managerial staff meetings
- department team meetings

External Communication:

The executive management ensures that appropriate external communication concerning the quality management system is made to relevant external interested parties. Typically, Investors receive communication from the corporate level by the Investor Relations office and through consolidated annual reports. Customer

communication is from the Customer Service Department and Sales and Marketing Departments via telephone, email, and on-site visits. Supplier communication is typically through the Material Department and Quality Assurance Department via telephone, email, reports of quality and delivery, etc. Communication with the community is made by Plant Management and the Human Resources Department via telephone, letter, email, and various community fund raising programs spear headed by the facility Activities Committee.

4.4.1. Customer Notification of Change to Organization

The Sales Department when required by customer or contract is to provide timely notification to customers of any changes in its organization affecting manufacturing processes & equipment's and/or QMS certification such as but not limited to:
- Regulatory Authorities
- Facility permits and registration status
- Approved sub-tier suppliers and sub-contractors
- Manufacturing Site or Location change
- Any other changes affecting the supplier scope of approval

4.5. DOCUMENTED INFORMATION

The AMETEK STC quality management system is a documented quality system established to ensure that all products conform to specified requirements.

4.5.1. General

The quality management system documentation includes documented statements of the quality policy and objectives, a quality manual, documented procedures required by ISO 9001, supplemental documents needed to ensure effective planning/operation/control of processes and required records.

Documented information is in the form of paper, microfiche, and electronic media.

4.5.1.1. AMETEK STC maintains a Quality Assurance Manual which defines the scope of the quality management system, the documented procedures or references to them defining the details of the system, and a description of the interaction between the processes of the quality management system.

4.5.1.2. Preparation and distribution of Quality Assurance Manuals and procedures:

GENERAL - The Quality Assurance Manager or designee is responsible for issuance and control of this manual including revisions.

PREPARATION - Following preparation by the Quality Assurance Manager and final approval by Staff, the Quality Assurance Manager will explain those procedures applicable to the affected department group leader. It is important that all those affected are made aware and fully understand the procedures.

AMENDMENTS AND REVISIONS - The Quality Assurance Manager is

responsible for all amendments and revisions to the manual. Departments initiating changes which may affect the procedures shall utilize the established document control system to request such changes. The date of the change is placed in the upper right of the page under the revision number.

OTHER DOCUMENTS - When necessary, in the judgment of the Quality Assurance Manager, other comprehensive documents relating to quality assurance may be originated. There are many quality assurance related documents of a specific nature, such as inspection records, purchasing files, etc.

REVIEW - The QA manual will be reviewed and as necessary to reflect current practices and conformance to current requirements.

DISTRIBUTION OF PROCEDURES - Copies of the Quality Assurance Manual, , may be made for submission to prospective customers whose purchase requirements include review of the AMETEK STC Quality Assurance Program.

The interaction between the processes of the quality management system is graphically depicted in Figure 2.

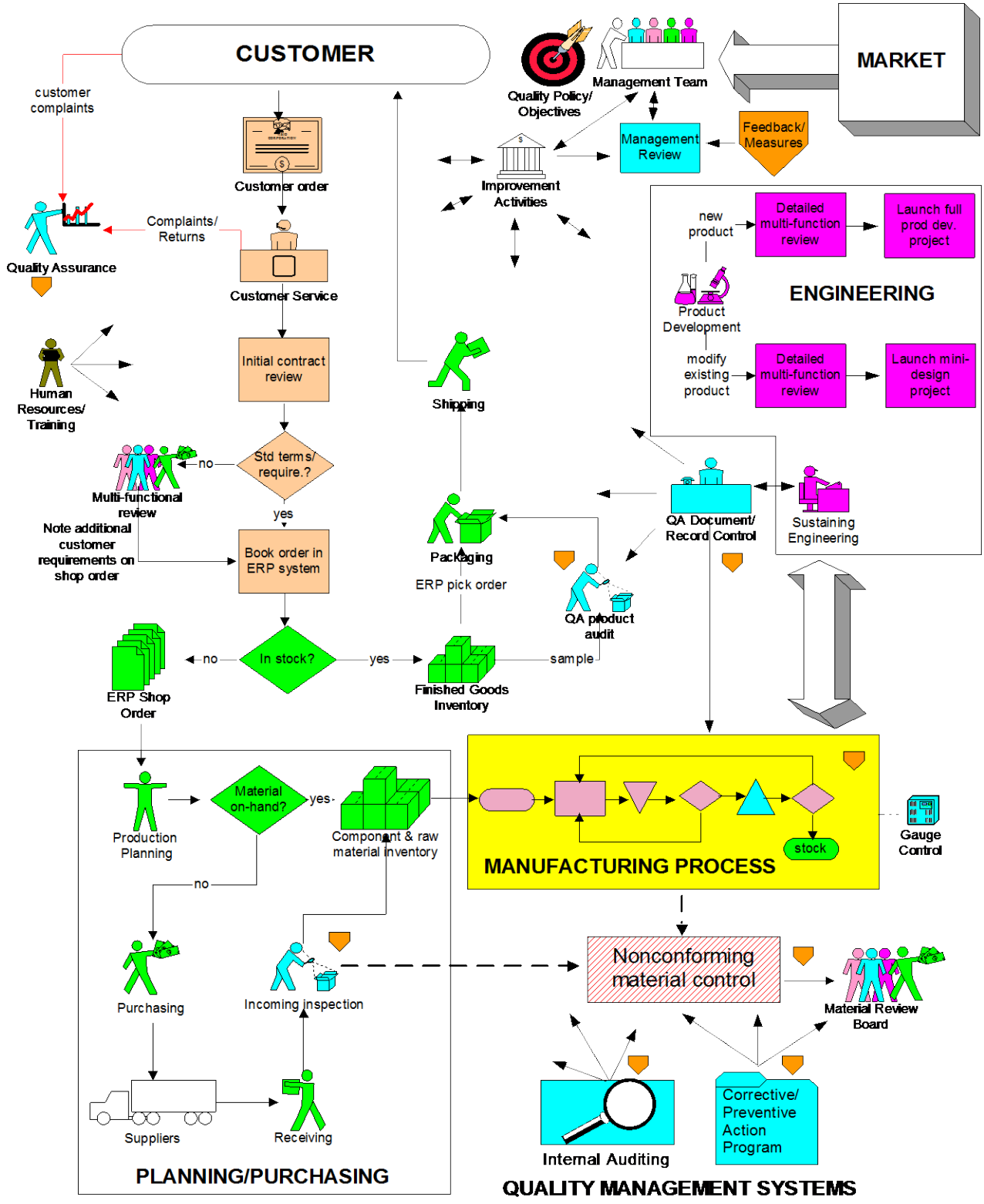


FIGURE 2 – INTERACTION OF PROCESSES

4.5.2. Creating and Updating

Document changes are reviewed and approved by the same authority as original approval, unless specifically designated otherwise.

Document changes are reviewed and approved by a designated organization with access to pertinent background information as required.

The document changes are marked, highlighted, or made apparent by other techniques in the document and identified in the release attachments.

4.5.3. Control of Documented Information

The purpose and scope of quality system documents is defined. All documents are reviewed and approved prior to issue. Appropriate documents are available at locations where they are readily available. The Quality Assurance Manager is responsible for coordinating, enforcing and auditing the document control related activities. Documents of external origin, such as standards and customer drawings, are controlled by the responsible department.

4.5.3.1. Quality System Documentation

4.5.3.1.1. Quality system documentation comprises the following types of documents:

- Quality Assurance Manual
- Operating procedures
- Work instructions and process procedures
- Standards and other reference material
- Product drawings and specifications
- Production and quality plans.
- Records

4.5.3.1.2. Document and data approval and issue Obsolete documents are promptly removed from use or otherwise identified, signed and dated to prevent unintended use.

Quality control and engineering records shall be retained to furnish evidence of the activities affecting product quality. Quality records demonstrate the achievement of the required quality and the effective operation of the quality system.

- Records will be legible.
- Records will be readily retrievable and stored in an environment to prevent damage, deterioration and loss.
- Retention periods for records are established and documented.
- Records will be made available to the purchaser as required.

5. OPERATION

5.1. OPERATIONAL PLANNING AND CONTROL

AMETEK STC plans for and develops processes consistent with the requirements of the quality management system to produce products conforming to customer requirements. In planning for the realization of product, quality objectives and customer requirements are determined, and sufficient processes, documentation, and resources are implemented to meet these objectives and requirements.

Processes are documented in procedures, work instructions, specifications, drawings, and manufacturing routers. AMETEK STC utilizes an Enterprise Requirements Planning (ERP) system for production planning, the procurement of raw materials, receiving, inventory management, scheduling of manufacturing orders, issuance of manufacturing orders to production, order tracking, and order fulfillment.
Manufacturing models utilized are discrete manufacturing and demand flow manufacturing.

Required verification, validation, monitoring, inspection, and test activities along with associated acceptance criteria are documented as instructions on manufacturing routers, drawings, specifications, work instructions, and procedures. Customer specific verification requirements are identified through contract review and are flowed down to the production function upon acceptance of the contract.

Records are maintained per a documented procedure providing evidence of verification, validation, monitoring, inspection and test activities conducted demonstrating product conformance to requirements.

5.2. REQUIREMENTS FOR PRODUCTS AND SERVICES

5.2.1. Customer Communication

An established Customer Service department exists in which Customer Service Representatives are available during normal business hours to answer questions and enquiry's concerning products, handle contracts or orders, handle amendments to existing orders, and take customer feedback including customer complaints. Communication media include telephone, fax, and e-mail. Customer Service Representatives are supported by all employees in the company, and they are free to query employees for help in customer issues including transfer of customer to employees in appropriate functional areas to assist the customer.

Customer complaints are reviewed and investigated. Formal corrective action requests are generated and assigned to appropriate personnel for root cause analysis, corrective actions, and preventive actions when warranted or when requested by the customer. The corrective action loop is closed by verification of action effectiveness.

In addition, AMETEK SCT maintains internet sites were customers may go for product information and literature, contact information, or on-line submittal of questions/comments/complaints.

5.2.2. Determining the Requirements for Products and Services

Customer specific requirements, including the requirements for delivery and post-delivery activities, are determined through a documented contract review process. Upon acceptance of a contract, purchase order, etc., an order acknowledgment is sent to the customer and these specific requirements are flowed down to the appropriate functions to be executed as part of the order.

In addition to customer specific requirements determined at the time of order, other requirements for standard products and services deemed necessary by AMETEK STC related to proper product function, statutory and regulatory requirements, and additional requirements are identified by appropriate functional departments and incorporated into the quality system documentation as part of the routine realization of product.

5.2.3. Review of the Requirements for Products and Services

Contracts are reviewed to ensure that processes and equipment have the capability to manufacture each product to the required specifications.

Contracts are distinguished as Sales Orders, Repair Orders, Demo Orders, Warranty Orders and Credit Orders. All contracts are reviewed for the following characteristics and features:

- requirements are adequately defined and documented
- required changes are documented, acknowledged, approved and dated
- order reviews are documented, acknowledged and dated

Verbal orders are not permitted. Records of contract review results and actions are maintained. Where the customer provides no documented statement of requirement, an order acknowledgement is sent to the customer as confirmation prior to order acceptance.

5.2.4. Changes to Requirements for Products and Services

Any changes that are made to the requirements for products and services require customer amended contracts or purchase orders to be submitted. These are reviewed with respect to the changes. Upon agreement to any changes, an amended Sales Order will be generated, and records of the amended customer purchase documentation, review of the amended purchase documentation, and amended Sales Order are maintained by the Customer Service Department. Amended order detail is flowed down to the production or service function via amended work orders, amended production lists, etc.

5.3. DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

5.3.1. General

Procedures have been established to ensure that the design process is a planned activity. Design activities are identified, and qualified personnel are assigned specific design responsibilities, and organizational interfaces are defined and controlled. Design input is formally documented and reviewed. The design is verified and, when applicable, is validated with prototype testing. The design output is documented and checked before it is released for production. Design changes are controlled according to procedure.
Information from previously designed products is used in the design of new products where applicable.

Application

This section applies to design and development of new products and product improvements, both hardware and software. This section directly concerns the Design Engineering department and departments interfacing with it, such as Marketing, Purchasing, Production, and Quality Assurance.

AMETEK STC designs its own standard catalog products as well as customer-specified products and modifications, and in some cases, contracts with external organizations for product design or design modification. Design Engineering is responsible for this task.

The Design Build Team (DBT) is a cross-functional team. It has the authority to design products and processes. It makes technical and business decisions supported by risk, time, value and cost analysis. The team has the authority to solicit participation by other company personnel and outside consultants.

5.3.2. Design and Development Planning

Every design project is managed by a Project Manager who is ultimately responsible for all aspects of the project.

The Project Manager is responsible for establishing a design plan prior to commencement of any design activities. The plan divides the design process into Stages: identifies design activities, assigns responsibilities for carrying out each specific activity, and specifies the design verification requirements. The plan also schedules design and verification activities, including design reviews.

Design personnel are qualified in the following skills as appropriate:

- Geometric Dimensioning and Tolerancing (GD&T)
- Design for Manufacturing/Design for Assemble (DFM/DFA)
- Value Engineering (VE)
- Design of Experiments (DOE)
- Failure Mode and Effects Analysis (FMEA)

- Solid Modeling
- Simulation Techniques
- Computer Aided Design / Computer Aided Engineering (CAD/CAE)

Organization and Technical Interfaces

The project manager is responsible for organization and technical communication between DBT members, and for ensuring that the project is on schedule. Additional duties include maintaining documentation and dissemination of information.

Personnel assigned to the DBT are qualified in skills and techniques appropriate to their activities. Each team member is responsible for taking full ownership of the tasks assigned and of completing those tasks in compliance with the project schedule.

5.3.3. Design and Development Inputs

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

5.3.4. Design and Development Controls

Design and Development Review

A design review will be conducted at predetermined stages and scheduled in the design project plan. The design review will be initiated by the project manager 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 and will be documented.

Design and Development Verification

The purpose of design and development verification is to demonstrate that the design output meets the design input requirements. This may include a prototype program.

At a minimum, the design is verified 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 and comparing the new 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. Design verification is concluded with complete layout inspection, material testing, and performance testing of products that have been manufactured during the production pilot run.

For complex new products, and when there is no experience with similar products, the design is verified by a prototype build and testing.

The prototype is built to be as close as possible to the final product. Whenever possible and practical, the same materials, subcontractors, tooling, and processes are used. Prototype testing will focus on verification of Special Characteristics and performance, including product life, reliability and durability.

A Pilot Build will be used to verify and validate production process methods, operations, sequence of events, tooling and features.

Records of design and development verification are maintained. Any design failures discovered throughout the verification process are documented and fixed using corrective and preventive actions.

Design and Development Validation

The purpose of design and development validation is to demonstrate that the designed product performs satisfactorily under real conditions by end-users 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.

Design and development validation activities are identified in the design project plan. Production processes and readiness for mass production are also validated. Design validation is concluded with performance testing of products that have been manufactured during the production pilot run.

Records of design and development validation are maintained. Any design failures discovered throughout the validation process are documented and fixed using corrective and preventive actions.

Design Transfer

AMETEK STC maintains procedures to ensure that the product design is correctly translated into production documentation. Appropriate bills of material, production routers, assembly instructions, test and calibration procedures, tools and fixtures, etc. are generated. Production personnel are trained to the production documentation. A production pilot build using components purchased through the normal purchasing process for production units representing typical components which will be received are used in the pilot build along with the production documentation. The pilot units are inspected and tested per the product specifications. Feedback in the inspection/test results and manufacturability of the product is given to Engineering.

Design History Documentation

The Engineering Project File is maintained by Engineering and contains or references all records related to the product design including all activities and documentation to demonstrate that the design was developed in accordance with the approved design plan and any other requirements specified for the product such as regulatory requirements. All original records and record revisions per design control procedures are maintained in the Engineering Project File.

Design and Development Outputs

The design process includes efforts to simplify and optimize the product and implement innovative solutions. The process also focuses on reduction of production cost 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, appropriate information for purchasing, instruct how to manufacture it, and instruct how to service it. These documents include drawings, specifications, procedures, required software, workmanship standards, acceptance criteria, process operator instructions, and so forth, and specify the characteristics of the product that are essential for its safe and proper use.

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 Manager 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 those documents generated during the design implementation phase that are subsequently transferred to procurement, and production, test 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 processes.

5.3.5. Design and Development Changes

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.

Design Change Scope

Design changes are considered changes after the 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 will be considered for new product development planning.

Change requests may circulate with “marked-up” documentation initialed and dated by authorized personnel and defining the purpose and scope of change. Initiation of a revision request can be done by any AMETEK STC colleague at which time the review process begins by way of the prescribed distribution. Approval of the revision request form is verification of the design change review. The amount of final verification and validation 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 a written approval or waiver of such approval. Design changes may not be implemented without written approval from the customer. Impact of a design change is always investigated and discussed with the customer. All customer-specific product design information is kept strictly confidential and is not released externally to anyone without the written authorization of the customer.

Engineering design documents will be identified with the project identification number, dated and filed in the Engineering Project File.

5.4. CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

5.4.1. General

Purchased products and services are obtained to specified requirements by using subcontractors who can meet these requirements. A record is maintained by purchasing that lists acceptable suppliers by commodity.

Assessment of Suppliers

Suppliers will submit a Supplier Questionnaire which in turn will be approved by Quality Assurance prior to purchase orders being placed.

Audits may also be conducted at the discretion of the Purchasing, Engineering or Quality Assurance on any supplier as necessary or when conformance to an element of the program is suspect, to verify the implementation and effectiveness of corrective action, prior to the award of a contract or purchase order if required.

The Quality Assurance department shall have the authority to veto the selection of any supplier if their ability to supply goods or services at the appropriate quality is in doubt before the award of a contract or purchase order.

5.4.2. Type and Extent of Control

Verification of Purchased Products

The Quality Assurance Manager or designee is assigned the responsibility to verify at source, or upon receipt that purchased product conforms to specified requirements.

5.4.2.1. Receiving Inspection and testing

Incoming products are not used or processed until they have been inspected or verified as conforming to specified requirements.

Historical inspection records, complexity and the intended use of the product for vendor provided product will serve as evidence of the degree of control by the

supplier and will guide the criteria for inspection at receipt.

When the Materials Manager, Quality Assurance Manager or the designee chooses to carry out verification at the supplier's plant, verification conducted by AMETEK STC shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection. Verification at the supplier's plant shall not be used by the supplier as evidence of effective control of quality by the supplier.

5.4.3. Information for External Providers

Purchasing documents for ALL purchased material contain data that clearly describes the product ordered including, where applicable, the type, class, style, grade or other precise identification, the name and part number, the revision level of the item ordered, any quality system standards to be applied to the product, and any paperwork or certification pertinent to the subsequent use of the product. Unconfirmed telephone orders are not permitted.

When specified, AMETEK MCT shall be afforded the right to verify at source or upon receipt that the purchased product conforms to specified requirements. The intended verification arrangements and method of product release will be specified in the purchasing documentation.

Purchasing documents are reviewed and approved for adequacy of the specified requirements prior to release.

5.5. PRODUCTION AND SERVICE PROVISION

5.5.1. Control of Production and Service Provision

Production, installation and servicing processes that directly affect quality are identified and planned to ensure that they are carried out under controlled conditions that include computer printed routers and follow reference standards/codes, drawings, quality plans, and/or documented procedures.
These procedures provide the necessary steps to build, test, and/or calibrate each product to the specified requirements using suitable production installation, servicing equipment, and a suitable working environment.

5.5.1.1. All products manufactured at AMETEK STC are processed under controlled conditions using computer-printed routers, drawings and manufacturing procedures. These procedures provide the necessary steps to build, test, and/or calibrate each product to the specified requirements.

5.5.1.2. A criterion for workmanship, which shall be stipulated in the clearest practical manner (i.e. written standards, representative samples, drawings or illustrations will be used).

5.5.1.3. Suitable maintenance of equipment to ensure continuing process capability will be performed.

5.5.2. Identification and Traceability

5.5.2.1. Processes will be established and maintained to identify product from receipt through all stages of production, delivery and installation, as appropriate.

All materials, parts, and assemblies are identified by the unique part number, lot number, serial number, router, traveler or other method as required by the design.

Note: The identification can be by a tag or label attached to the object or records on the container(s), flats or racks where the objects are stored, or files traceable to the material.

Parts requiring material control and traceability are marked or tagged with material identification codes or customer supplied identification numbers. Records of these parts are maintained.

Materials or parts that cannot be identified are considered nonconforming materials and will be processed in accordance with Section 7.2.

5.5.2.2. Material traceability

All materials requiring traceability of origin and/or composition shall be identified throughout the transformation process. Metals or composite materials must have chemical and physical certificates where appropriate.

5.5.2.3. Inspection and test status

The identification of inspection and test status is maintained throughout the process. Inspection and test status of product will be done by using inspection stamps, tags, routers, labels, inspections records, test results, or by physical location. Records will indicate the authorized inspection personnel responsible for the release of conforming product. Status identification will be controlled as necessary, throughout production and installation to ensure only acceptable product is shipped, used or installed.

5.5.3. Property Belonging to Customers or External Providers

AMETEK SCT identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. Records of customer property are maintained. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer in a timely fashion and recorded on internal records.

5.5.4. Preservation

Process are established to control the handling, storage, packaging, preservation and delivery of product for all storage areas.

5.5.4.1. Handling - Methods are provided to prevent damage and deterioration during handling.

5.5.4.2. Storage - Materials, parts and assemblies are stored on racks, pallets, bins, or other means to prevent damage, rust, corrosion and deterioration.

The issue and receipt of goods to and from secured storage areas are controlled and stored products are assessed at appropriate intervals.

All components and assemblies will be cleaned of dirt, cutting oil, metal chips and other contaminants.

Limited shelf life parts are identified, labeled and stored to protect and control the product shelf life.

Exposed sealing surfaces are protected from mechanical damage before shipping.

Material will be segregated if required by specification or customer.

5.5.4.3. Packaging - All packaging will be in accordance with specific procedures 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.

5.5.4.4. Preservation - Products are identified, preserved and segregated from time of receipt until responsibility ceases.

5.5.4.5. Delivery - Products are delivered to the shipping area for destination packaging, marking and protection.

Protection is provided from delivery to destination as required.

5.5.5. Post-delivery Activities

AMETEK STC supports the products and services delivered to its customers. Warranties are provided to assure customers of receiving defect free products and services and are in accordance with company policies along with statutory and regulatory requirements. In addition, routine servicing of products in support of customers is offered along with services such as training in the use of products. Customer feedback, both positive and negative, is solicited and used to continually improve the quality of products and services along with the quality management system in general.

5.5.6. Control of Changes

Processes utilized in production or in services offered are adequately controlled. These processes are defined in authorized procedures, work instructions, production routers, and other controlled documentation.
Process changes undergo a review and approval cycle similar to product changes. The proposed change or changes are reviewed by individuals authorized by the company to approve such changes. Consideration of any negative effects are given during this

review along with consideration of maintaining compliance with statutory and regulatory requirements along with customer requirements. Records are retained showing the change(s), the results of the review of the change(s), the person(s) authorizing the change, and any actions taken as a result of the change(s) including revised process documentation. Once changes are authorized, appropriate personnel involved in the process are notified of the changes and receive appropriate training as required.

5.6. RELEASE OF PRODUCTS AND SERVICES

Various mechanisms are in place at appropriate stages within the various production processes or service processes to verify requirements have been met. These include final acceptance testing, final calibration for test and calibration instruments, peer inspection, Quality Assurance product auditing, and customer source inspection.
Products or services that fail to meet the established requirements for acceptance are reworked and re-evaluated to verify applicable requirements have been met. Products or services that do not conform to specification requirements are identified as nonconforming, and an inspection report is generated with the nonconformities noted. These are submitted to a formal Material Review Board for review and disposition whose members have been authorized by the company to decide on release or other measures such as repair to lessen nonconformity impact unless a contract with a customer prohibits such action in which case the customer is involved in the decision-making process.

Records of inspections, tests, and product audits providing evidence of conformity with the acceptance criteria and including traceability to the person(s) authorizing release are retained.

5.7. CONTROL OF NONCONFORMING OUTPUTS

5.7.1. 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 including customer notification or recall of product.

5.7.2. AMETEK STC shall retain documented information that:

- describes the non-conformity;
- describes the action taken;
- describes any concessions obtained;
- identifies the authority deciding the action in the respect of the nonconformity;

6. PERFORMANCE EVALUATION

6.1. MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

6.1.1. General

AMETEK STC employs appropriate process and product inspection and test points to adequately monitor and control processes and establish product conformance to the specifications. Conformity to the quality management system is evaluated through the quality levels obtained of process and product appraisal, customer feedback, internal auditing and third-party auditing. Continuous improvement of the quality management system's effectiveness is on-going and ultimately demonstrated by customer satisfaction input to the products and services being provided.

6.1.1.1. Monitoring and Measurement of Processes

Suitable methods for monitoring processes by monitoring process parameters or product characteristics are employed where applicable and may include statistical process control, machine control or auditing. These methods shall demonstrate the ability of the processes to achieve planned results.

When process parameters indicate process drift toward out-of- control conditions, corrections will be applied to maintain process control. When planned results are not achieved, corrective actions are taken as appropriate to ensure conformity of the product.

6.1.1.2. Monitoring and Measurement of Product

Processes for inspection and testing activities are established and maintained to verify that the specified requirements for the product are met. Inspection and Test records are established and detailed in the quality plan and/or documented procedures.

In-process inspection and testing

Products are inspected and tested as required by the quality plan and/or documented procedures.

Products are held until the required inspection and tests have been completed or reports have been received and verified, except when the product is released under positive-recall procedures.

Final inspection and testing

Specified final inspection and testing is done in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product.

The quality plan and/or documented procedures for final inspection and testing require that all specified inspection and tests, including those specified either on receipt of product or in-process, are carried out and that results meet specified

requirements.

Inspection and test records

Records are established and maintained which provide evidence that the product has been inspected and/or tested.

The records clearly show whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.

Documented procedures for the control of nonconforming products apply where the product fails to pass any inspection and/or test.

The records identify the authorized inspection personnel responsible for the release of the product.
AMETEK STC recognizes that the customer has the right to inspect their products at AMETEK STC or at a subcontractor's facility, if specified in the contract or purchase order. AMETEK STC will make available personnel, and inspection equipment as required.

6.1.2. Customer Satisfaction

Customer satisfaction is routinely measured by monitoring of on time delivery performance, tracking warranty returns for product performance trends, monitoring customer feedback including complaints. Other methods of gauging customer satisfaction are employed periodically and involve on-site customer visits, solicited customer feedback via telecommunications (phone, fax, e-mail), customer conferences, and customer satisfaction surveys.

6.1.3. Analysis and Evaluation

As part of the effort for continual improvement of the effectiveness of the quality management system, data collected as a result of the feedback, monitoring, and measurement systems is collected and analyzed to determine suitability of current processes and opportunities for process improvement. Data collected relates to customer satisfaction, product conformity, characteristics and trends of processes and products, and suppliers. Analysis may be performed using graphical, statistical, or other suitable techniques. The sources of the data at a minimum are as follows:

- Returned Material Authorizations (RMA’s) and Product Quality Reports (PQR’s)
- Final Inspections, Peer Inspections, Test Results, Calibration Results
- In-process Inspections, Statistical Process Control, Process Studies
- Internal Audits and Supplier Audits
- Corrective and Preventive Actions issued
- Incoming Inspection

6.2. **INTERNAL AUDIT**

6.2.1. Internal audits are conducted at planned intervals and will be used to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality management system and the requirements of ISO-9001.
The Quality Assurance Department will prepare an audit schedule to define the system audits scheduled

6.2.2. The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as previous audit results. The area to be audited, audit scope and scheduled completion date are documented in an audit schedule for each calendar year assuring all elements of the quality system are covered.
Selection of auditors will be made to ensure no bias in the audit process.
Audits are conducted in accordance with written checklists or working procedures but are not necessarily limited by the scope of the checklists. Audits are performed by appropriately trained personnel not having direct responsibility for the areas that are audited. Management for the audited area is responsible to ensure that corrective actions are effective through prompt follow-up action. Follow-up action includes the verification of actions taken and the reporting of verification results.

The Quality Assurance manager has responsibility to plan, schedule and ensure internal audits are conducted per schedule. He also is responsible for ensuring responses by responsible individuals are documented including corrective actions and all follow-up action including verification activities that is necessary to ensure effective corrective action are completed. The Quality Assurance Manager is to ensure that the results of the audits are reported to management.

6.3. MANAGEMENT REVIEW

6.3.1. 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 STC quality system, 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.

6.3.2. Management Review Inputs

Management review input will consist of the following inputs:

- follow-up actions from previous management reviews;
- changes in internal and external issues that are relevant to the Quality Management System;
- customer satisfaction and feedback from relevant parties;
- The extent to which quality objectives have been met.
- process conformance and product conformity

- nonconformities and corrective actions,
- monitoring and measurement results
- audit results
- the performance of external providers
- adequacy of resources
- effectiveness of actions taken to address risk and opportunities
- opportunities for improvement
- effectivity of the QMS with respect to hazardous location products

6.4. Review Outputs

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

- Opportunities for improvement;
- Any need for changes to the quality management system;
- resource needs.

The quality assurance manager is responsible to issue minutes of the management review.

7. **IMPROVEMENT**

7.1. **GENERAL**

Opportunities for improvement are determined by the organization by reviewing inputs such as customer feedback, customer complaints, process monitoring, inspection and test results, internal auditing, and management reviews. Products and services are reviewed against competitive offerings and market need to assure customer expectations are met. When problems are encountered, corrections are made with an emphasis on taking care of the customer, and preventive measures are sought out and implemented to avoid repeat occurrences of problems and address the consequences related to these issues. AMETEK STC looks continually improve its products and services and the performance and effectiveness of the quality management system.

7.2. NONCONFORMITY AND CORRECTIVE ACTION

Corrective Action

Corrective actions are taken to eliminate the recurrence of causes of actual nonconformities to a degree appropriate for the magnitude of the problems and commensurate with the risks encountered.

Corrective actions are documented and completed by the affected department manager. Repetitive nonconforming conditions will require a Corrective Action Report (CAR).

Internal Corrective Actions

Internal corrective actions are issued as a result of product nonconformance, negative trends, audit findings, and customer complaints. Corrective actions are to be completed by the affected department manager including verification of action effectiveness. The Quality Assurance Manager is responsible for follow-up to ensure that action was concluded and eliminated the cause of the nonconformance.

External (Supplier) Corrective Actions

External corrective actions are issued as a result of supplier product nonconformance, negative trends, and supplier audit findings. Corrective actions are to be completed by the supplier. The quality Department designee is responsible for follow-up to ensure that action was concluded and eliminated the cause of the nonconformance.

Products that are nonconforming are investigated to determine the root cause. Minor problems are corrected immediately, and major problems are cause for rejection using the standard Inspection Report (IR).

7.3. **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.

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	440-0015-138	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
16	Supplementary QMS Requirements for ATEX / IECEx	440-0018-551	N/A
17	ITP Inspection and Test Plan Template to address the requirements of CSA N299.3	440-0118-888	N/A
18	Quality Program Category Selection template to address the requirements of CSA N299.3	440-0118-889	N/A
19	Supplement to Quality Manual 440-0018-095 to address the requirements of CSA N299.3	440-0018-820	N/A