



AS 9100 Quality Systems Manual

**80 Collingsdale Drive
Milford, CT 06461-3005**

Revision A

Introduction

Newhart Products developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Newhart Products meets the requirements of the international standard SAE AS9100 REV B as applicable to the products we manufacture.

The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2008 format and AS 9100 REV B. Each section begins with a policy statement expressing Newhart Products obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS 9100 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

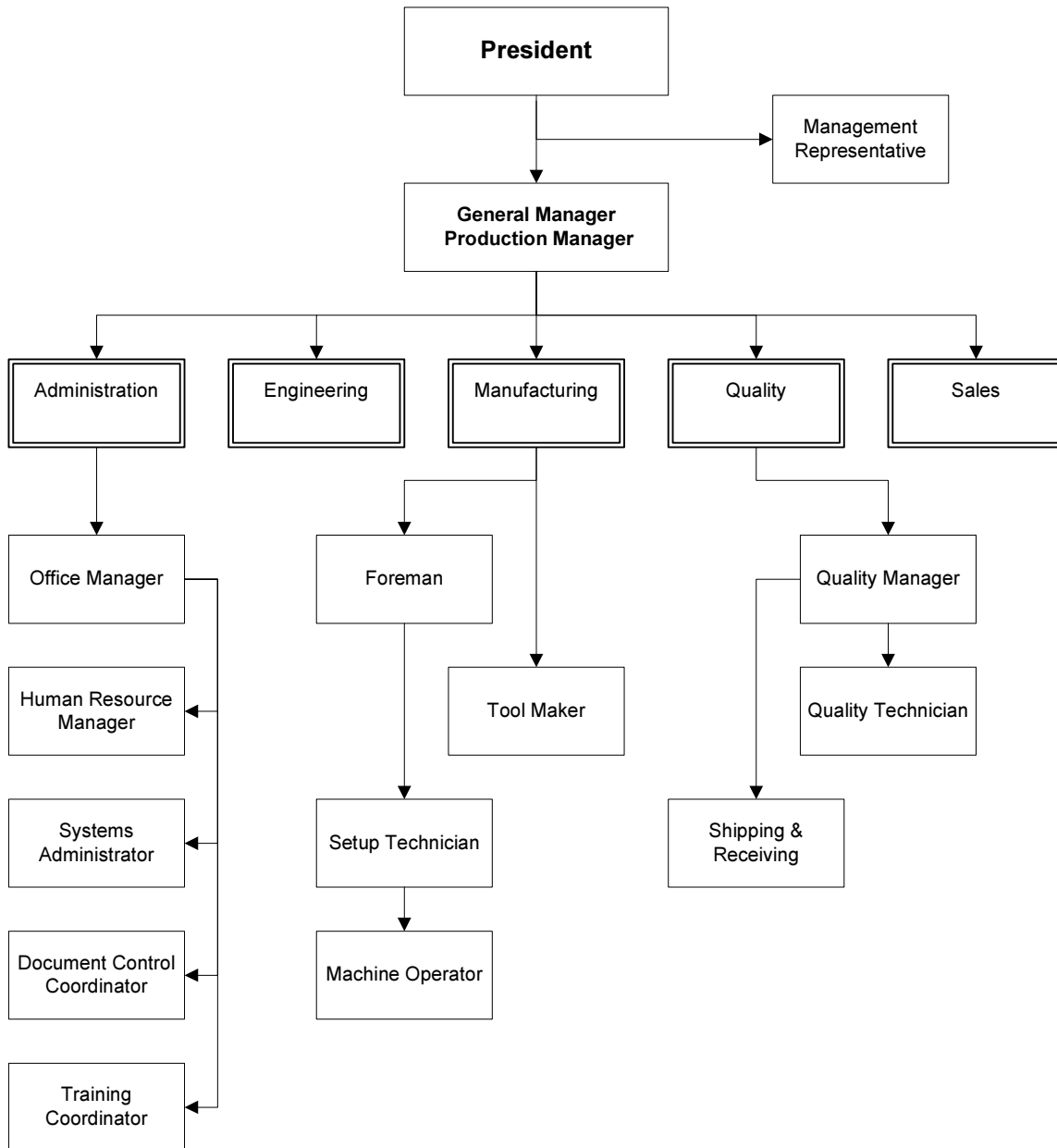
President: *Thomas N. D'Aulizio*

Quality Manual Distribution

The Quality Manual shall be made available to all employees via the Newhart Products intranet. All hard copies of this manual shall be considered UNCONTROLLED unless annotated otherwise.

A Copy of the Quality manual will be made available to Customers, Vendors, and Regulatory Agencies via the Company internet Website address:

<http://www.newhartproducts.com/quality.html>



Section 1: Scope

1.1 General

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard SAE AS 9100 Rev. B.

Newhart Products is an aerospace manufacturing company specializing in metal stamping, CNC machining, EDM and Water Jet cutting.

1.2 Application

Newhart Products has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- Clause 7.3, Design and Development: As a manufacture to print company, this facility does not offer or involve itself in the design and/or development of products, but only in the fabrication of products having existing proven designs provided by our Customers.
- Clause 7.5.1.5, Control of Service Operations: Newhart Products is not involved in, nor does it perform service operations. Therefore the quality management system requirements defined within paragraph 7.5.1.5, Control of Service Operations, does not apply to our organization and has been excluded from our quality management system.

Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS 9001/ASQ Q9000-2005, Quality Management Systems - Vocabulary.

Section 3: Definitions

3.0 Quality Management System Definitions

This section is for definitions unique to Newhart Products.

- Customer owned property -- Any type of instrumentation, accessories, tooling, manuals, intellectual property or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture of customer-owned property.
- Key Characteristics -- The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.
- Product – The end item result of meeting all contract terms and conditions.
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
- Outsourcing -- An arrangement in which a company provides services for Newhart Products that could also be or usually have been provided in-house.

AS9100 REV B Requirement Cross Reference Table

AS9100 REV B Reference	Reference Description	Quality Manual Reference	Procedure Reference	Form Reference	Work Instruction Reference
1.0	Scope	1.0			
2.0	Normative Reference	2.0			
3.0	Terms and Definitions	3.0			
4.0	QUALITY MANAGEMENT SYSTEM	4.0			
4.1	General Requirements	4.1			
4.2	Documentation requirements	4.2			
4.2.1	General	4.2.1			
4.2.2	Quality Manual	4.2.2			
4.2.3	Control of Documents	4.2.3	AP-423	F-423-003 F-423-004	
4.2.4	Control of Records	4.2.4	AP-424	F-424-001	
4.3	Configuration Management	4.3			
5.0	MANAGEMENT RESPONSIBILITY	5.0	AP-500	F-500-001	
5.1	Management Commitment	5.1			
5.2	Customer Focus	5.2			
5.3	Quality Policy	5.3	AP-501		
5.4	Planning	5.4			
5.4.1	Quality Objectives	5.4.1			
5.4.2	Quality Management System Planning	5.4.2			
5.5	Responsibility, Authority and Communication	5.5			
5.5.1	Responsibility and Authority	5.5.1			
5.5.2	Management Representative	5.5.2			
5.5.3	Internal Communication	5.5.3			
5.6	Management Review	5.6	AP-821	F-500-001	
5.6.1	General	5.6.1			
5.6.2	Review Input	5.6.2			
5.6.3	Review Output	5.6.3			

AS9100 REV B Reference	Reference Description	Quality Manual Reference	Procedure Reference	Form Reference	Work Instruction Reference
6.0	RESOURCE MANAGEMENT	6.0			
6.1	Provision of Resources	6.1			
5.2	Human Resources	5.2			
6.2.1	General	6.2.1			
6.2.2	Competence, Awareness and Training	6.2.2	AP-622	F-622-002 F-622-003 F-622-004	
6.3	Infrastructure	6.3	EP-630	F-630-001 F-630-002	
6.4	Work Environment	6.4			
7.0	PRODUCT REALIZATION	7.0			
7.1	Planning of Product Realization	7.1	MP-710	F-710-001 F-710-002	
7.2	Customer-Related Processes	7.2	SP-720		
7.2.1	Determination of Requirements Related to the Product	7.2.1			
7.2.2	Review of Requirements Related to the Product	7.2.2	EP-722		
7.2.3	Customer Communication	7.2.3		F-723-001	
7.3	Design and Development	7.3	N/A	N/A	N/A
7.4	Purchasing	7.4	AP-740		
7.4.1	Purchasing Process	7.4.1			
7.4.2	Purchasing Information	7.4.2		F-742-001	
7.4.3	Verification of Purchased Product	7.4.3			
7.5	Production and Service Provision	7.5	MP-750	F-705-001	
7.5.1	Control of Production and Service Provision	7.5.1			
7.5.1.1	Production Documentation	7.5.1.1		F-824-001	
7.5.1.2	Control of Production Process Changes	7.5.1.2	MP-750	F-751-001	
7.5.1.3	Control of Production Equipment, Tools and Numerical Control (NC) Machine Programs	7.5.1.3			
7.5.1.4	Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities	7.5.1.4			
AS9100 Reference	Reference Description	Quality Manual Reference	Procedure Reference	Form Reference	Work Instruction Reference

7.5.1.5	Control of Service Operations	7.5.1.5			
7.5.2	Validation of Processes for Production and Service Provision	7.5.2			
7.5.3	Identification and Traceability	7.5.3	MP-753	F-753-001 F-753-002	
7.5.4	Customer Property	7.5.4	MP-754		
7.5.5	Preservation of Product	7.5.5	MP-755		
7.6	Control of Monitoring and Measuring Devices	7.6	QP-760		
8.0	MEASUREMENT, ANALYSIS AND IMPROVEMENT	8.0			
8.1	General	8.1			
8.2	Monitoring and Measurement	8.2			
8.2.1	Customer Satisfaction	8.2.1	AP-821		
8.2.2	Internal Audit	8.2.2	QP-822	F-822-001 F-822-002 F-822-003	
8.2.3	Monitoring and Measurement of Processes	8.2.3			
8.2.4	Monitoring and Measurement of Product	8.2.4	MP-824	F-824-001	
8.2.4.1	Inspection Documentation	8.2.4.1			
8.2.4.2	First Article Inspection	8.2.4.2			
8.3	Control of Nonconforming Product	8.3	QP-830		
8.4	Analysis of Data	8.4	QP-840		
8.5	Improvement	8.5			
8.5.1	Continual Improvement	8.5.1			
8.5.2	Corrective Action	8.5.2	QP-852		
8.5.3	Preventive Action	8.5.3	QP-853		

Section 4

Quality Management System

4.1 General requirements

Newhart Products has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Newhart Products has:

- Determined the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual.
- Determined the sequence and interaction of these processes..
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective..
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
- Established systems to monitor, measure where applicable and analyze these processes..
- Established processes to determine and implement actions necessary to achieve planned results and continual improvement of these processes.

4.1.1 Outsourcing

Newhart Products currently outsources the internal auditing function. Additional processes that affect product conformity are not outsourced at this time. If Newhart Products elects to outsource then the requirements of AS9100 will be met.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures and records
- Documents identified as necessary for the effective planning, operation and control of our processes
- Quality Records
- Records required by statutory/regulatory authorities

Newhart Products ensures that personnel have access to quality management system documentation and are aware of relevant procedures. We also provide customer or regulatory authorities access to quality management system documentation.

4.2.2 Quality manual

This Quality Manual has been prepared to describe Newhart Products QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures where applicable, relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system. The relationship between the AS 9100 standard and documented procedure has been indicated by use of a numbering system that correlates to the AS 9100 standard.

4.2.3 Control of documents

All of the QMS documents are controlled according to the Document Control Procedure (AP-423). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin determined by Newhart Products to be necessary for the planning and operation of the quality management system are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose
- Obtaining customer / regulatory agency approvals when required by contract or regulatory/statutory requirements
- Coordinating document changes with customers or regulatory authorities in accordance with contract or regulatory/statutory requirements

4.2.4 Control of quality records

Quality records established to provide evidence of conformity to requirements and of the effective operation of the QMS shall be controlled. The records, including those created by or maintained by suppliers, are maintained according to the Control of Quality Records Procedure (AP-424). This procedure requires that quality records remain legible, readily identifiable and retrievable. Records are available for review by customers and regulatory authorities in accordance

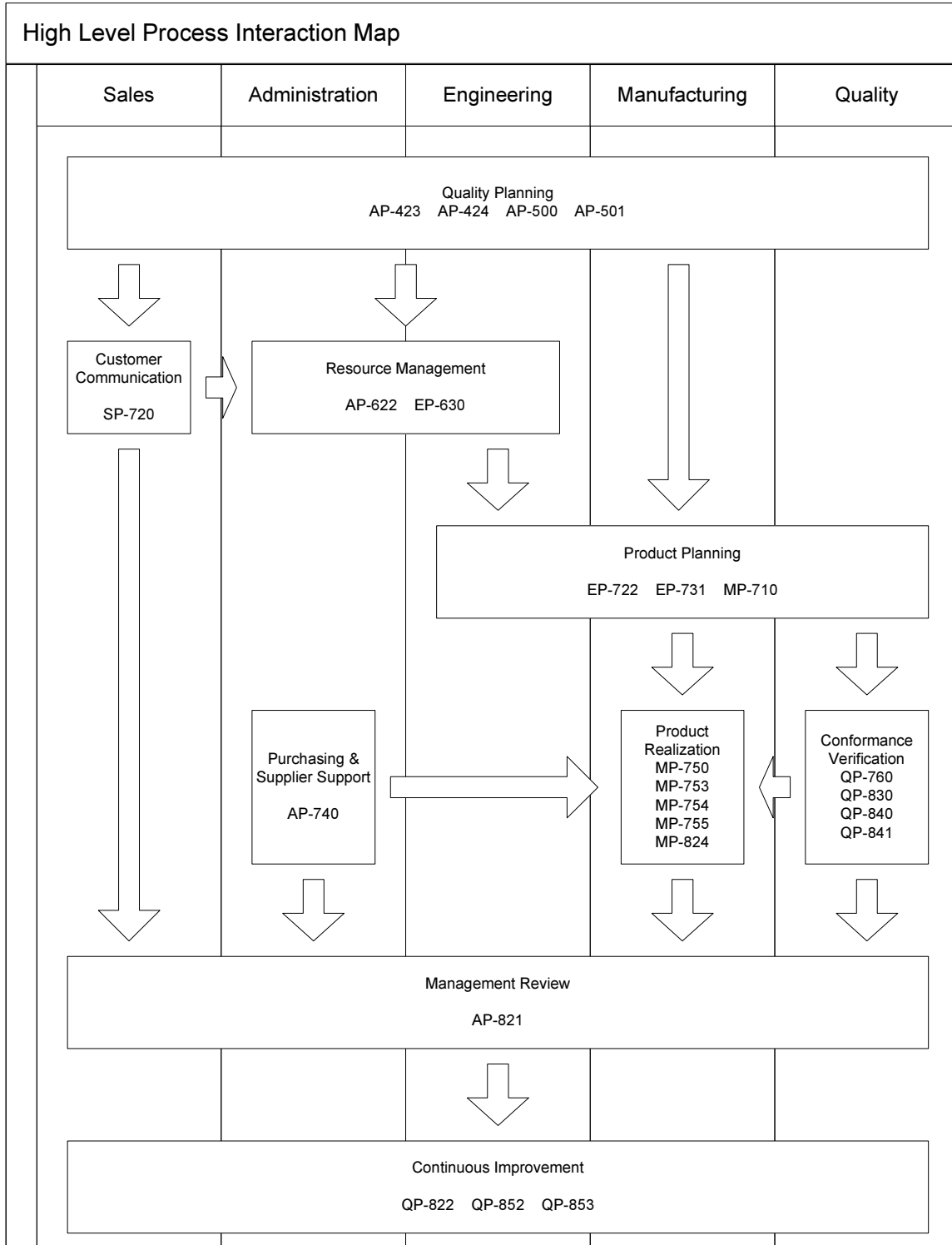
with contract or regulatory/statutory requirements. The procedure defines the controls needed for identification, storage, protection, retrieval, retention and disposition of quality records. Records are made available to customers / regulatory agencies when required by contract or regulatory requirements.

4.3 Configuration Management:

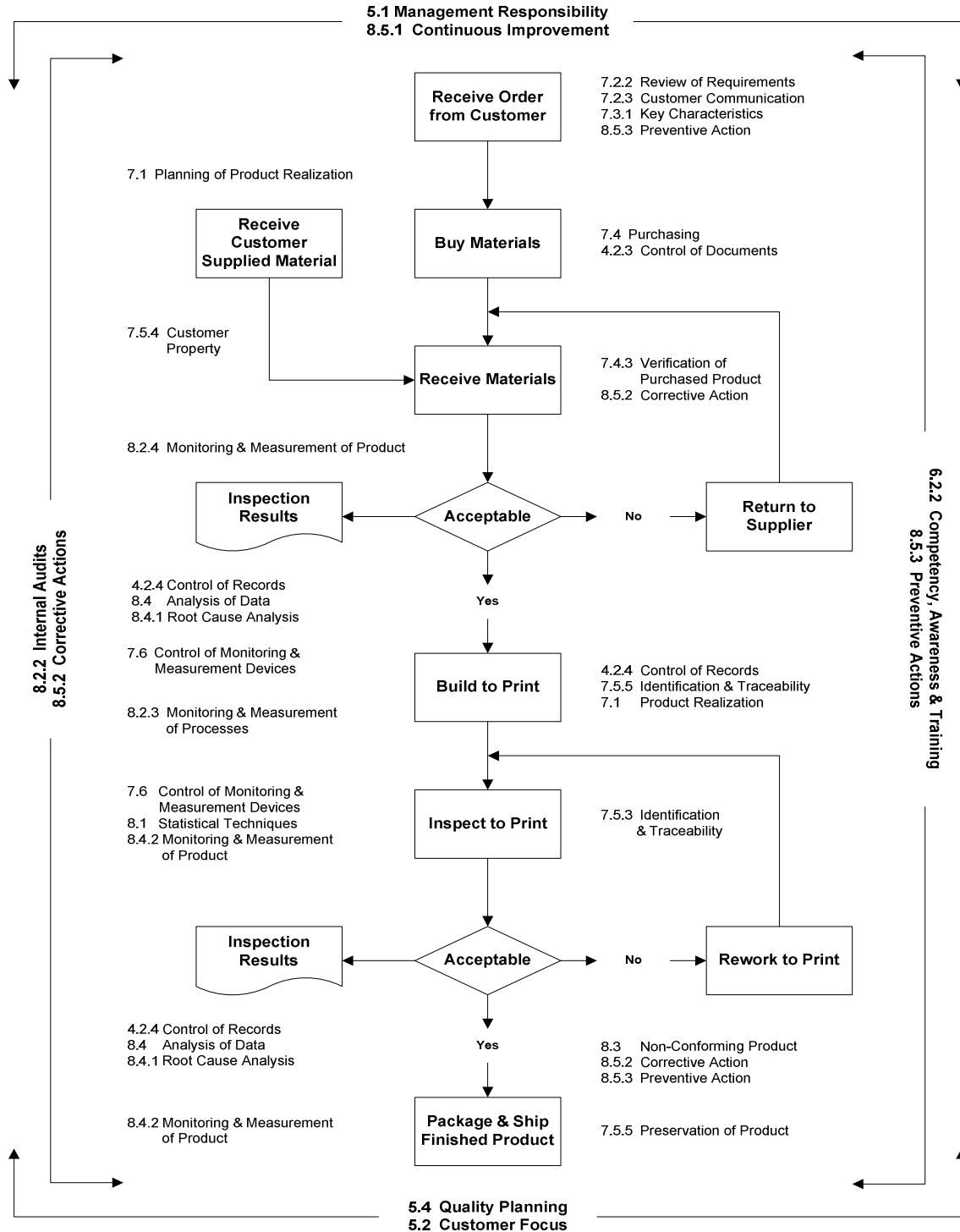
Newhart Products does not offer or involve itself in the design or development of products but rather manufactures products from existing designs and established configuration provided by our customers. Newhart Products shall maintain product configuration in accordance with customer contractual requirements.

Related Procedures

Document Control	AP-423
Control of Quality Records	AP-424



ISO QMS Process Flowchart



Section 5

Management Responsibility

5.1 Management commitment

Top management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct, at a minimum, yearly management reviews.
- Ensure the availability of resources.

5.2 Customer focus

Newhart Products strives to determine current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (SP-720).

5.3 Quality policy

“Newhart Products will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue ever improving quality through programs that enable each employee to do their job right the first time and every time.”

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy’s continuing suitability for our organization. The Quality Policy is documented in AP-501, Quality Policy.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy. Quality objectives are measurable, and reviewed against performance goals and continued suitability at each management review meeting.

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the AS 9100 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 4 of this manual.

5.5.2 Management representative

Newhart Products will appoint a member of management to act as the Management Representative having the following responsibility and authority to:

- Ensure that processes needed for the quality management system are established and implemented and maintained
- Report to top management on the performance of the quality management system, and note needed improvements
- Promote awareness of customer requirements throughout the organization
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS
- Resolve matters pertaining to quality issues
- Organizational freedom to resolve matters pertaining to quality

5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS may include department and management meetings, management review, prominent posting of current quality and delivery statistics, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

5.6 Management review

5.6.1 General

Top management reviews the QMS quarterly at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, determining opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement
- Quality Policy
- Resources

5.6.3 Review output

During these review meetings, management will determine appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs
- Quality objectives

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Related Procedures:

Customer Related Processes	SP-720
Management Responsibility	AP-500
Planning of Product Realization Processes	MP-710

Section 6

Resource Management

6.1 Provision of resources

Newhart Products has implemented a Quality Management System that complies with the AS 9100 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared determining the qualifications required for each position that affects product quality requirements. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with applicable training, provide the competence required for each position.

6.2.2 Competence, Training, and Awareness

Newhart Products:

- Determines the necessary competence for personnel performing work affecting conformity to product requirements,
- Where applicable, provides training or takes other actions to achieve the necessary competence,
- Evaluates the effectiveness of the actions taken
- Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- Maintains appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

To meet quality objectives and product requirements Newhart Products has determined the infrastructure needed (EP-630). The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment, information systems and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity.

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the

quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Related Documents

Competence, Awareness and Training	AP-622
Infrastructure	EP-630

Section 7

Product Realization

7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning takes place according to the Planning of Product Realization procedure (MP-710). During this planning, management or assigned personnel determine, as appropriate:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required,
- Verification, validation, monitoring, measurement, inspection and test requirements,
- Criteria for product acceptance,
- Resources necessary to support operation and maintenance of the product, &
- Resources to support operation and maintenance of the product.

The output of quality planning includes documented review sheets and job travelers.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Newhart Products determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer,
- Required for delivery and post-delivery activities,
- Not stated by the customer but necessary for specified use or known and intended use,
- Statutory and regulatory requirements applicable to the product,
- Additional requirements considered necessary by Newhart Products

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

7.2.2 Review of requirements related to the product

Newhart Products has a process in place for the review of requirements related to the product (SP-720). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Newhart Products has the ability to meet the defined requirements

- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, Newhart Products communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated.

7.2.3 Customer communication

Newhart Products has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information,
- Enquiries, contracts and order handling, including amendments, &
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and development planning

As a manufacture to print company, this facility does not offer or involve itself in the design and/or development of products, but only in the fabrication of products having existing proven designs provided by our customers. Based on this justification, the quality management system requirements defined within SAE AS9100 REV B paragraph 7.3, Design and Development do not apply to our type of operation and have been excluded from our quality management system.

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (AP-740) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records. The organization is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

7.4.2 Purchasing information

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

- Requirements for approval of product, processes and equipment,
- Requirements for qualification of personnel, &
- Quality management system requirements outlined in the Purchasing Procedure (AP-740)

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of purchased product

The Purchasing procedure (AP-740) describes the process used to verify that purchased product meets specified purchase requirements. Purchased product is not used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure. If test reports are used to verify purchased product, the data must meet applicable specifications. Test reports for raw material are periodically validated.

When verification activities are delegated to the supplier the requirements are defined, and a register of delegations is maintained.

If Newhart Products or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Where specified in the contract, the customer or the customer's representative is given the right to verify at the suppliers premises and organization's premises that product conforms to specified requirements

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Newhart Products plans and carries out production and service provision under controlled conditions according to documented procedure (MP-750). Planning considers, as applicable:

- The establishment of process controls and development of control plans where key characteristics have been identified,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- Special processes (see 7.5.2).

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product,
- The availability of work instructions,
- The use of suitable equipment,
- The availability and use of monitoring and measuring equipment,
- The implementation of monitoring and measurement,
- The implementation of product release, delivery and post-delivery activities ,
- accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product), part accountability to ensure bad parts have been destroyed,
- evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- provision for the prevention, detection, and removal of foreign objects,
- monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

7.5.1.1 Production Documentation

Production operations are carried out in accordance with approved data. This data contains as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents
- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.

7.5.1.2 Control of Production Process Changes:

Authorized people for approving changes to production processes are identified in the Procedure MP-750. Newhart Products identifies and obtains acceptance of changes that require customer or regulatory authority approval in accordance with contract or regulatory/statutory requirements. Changes affecting processes, production equipment, tools and programs are documented and procedures are available to control the implementation of changes.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. Storage requirements, including periodic preservation/condition checks, have been established for production equipment or tooling in storage.

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

When planning to temporarily transfer work to a location outside the organization's facilities, the organization defines the process to control and validate the quality of the work.

7.5.1.5 Control of Service Operations

Newhart Products is not involved in, nor does it perform service operations. Therefore the quality management system requirements defined within this paragraph do not apply to our organization and has been excluded from our quality management system.

7.5.2 Validation of processes for production and service provision

Newhart Products validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Newhart Products has documented the process for validation including:

- Defined criteria for review and approval of the processes, qualification and approval of special processes prior to use
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures,
- Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- Requirements for records
- Revalidation

7.5.3 Identification and traceability

Newhart Products identifies the product throughout product realization according to the Identification and Traceability procedure (MP-753).

- Newhart Products maintains the identification of the configuration of the product in order to determine any differences between the actual configuration and the agreed configuration.
- Product status is identified with respect to monitoring and measurement requirements throughout product realization.
- When acceptance authority media such as stamps, electronic signatures or passwords are used Newhart Products establishes and documents controls for the media.
- According to the level of traceability required by contract, regulatory, statutory or other established requirement, Newhart Products system provides for:
 - Identification to be maintained throughout the product life;
 - All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
 - For an assembly, the identity of its components and those of the next higher assembly to be traced;

- For a given product, a sequential record of its production (manufacture, assembly, inspection) to be maintained.

Newhart Products controls and records the unique identification of the product where ever traceability is a specified requirement

7.5.4 Customer property

Newhart Products exercises care with customer property while it is under the organization's control or being used. A procedure (MP-754) outlines the Identification, verification, protection and safeguarding of customer property, including intellectual property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

7.5.5 Preservation of product

Newhart Products preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements, per procedure (MP-755). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- Cleaning;
- Prevention, detection and removal of foreign objects;
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life control and stock rotation;
- Special handling for hazardous materials.

The organization ensures that documents required by the contract or order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of monitoring and measuring equipment

Newhart Products has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. A documented procedure (QP-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- Calibrated or verified or both 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 shall be 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
- Be recalled according to a defined method when requiring calibration

In addition, Quality assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Newhart Products takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

Newhart Products maintains a register of all monitoring and measuring equipment. The process used for their calibration is defined in procedures, work instructions and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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

Newhart Products ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Related Documents

Planning of Product Realization Processes MP-710

Customer Related Processes SP-720

Purchasing AP-740

Control of Production and Service Provision MP-750

Identification and Traceability MP-753

Preservation of Product MP-755

Control of Monitoring and Measuring Equipment QP-760

Section 8

Measurement, Analysis and Improvement

8.1 General

Newhart Products plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity to product requirements,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Newhart Products monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (SP-720) and the Management Responsibility procedures (AP-500).

8.2.2 Internal Audit

Newhart Products conducts internal audits at planned intervals to determine whether the quality management system:

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, &
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (QP-822).

The management responsible for the area being audited is responsible for ensuring that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Detailed tools and techniques such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements are developed, maintained and used according to the Internal Audit Procedure (QP-822). The acceptability of the selected tools is measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits meet contract and/or regulatory or statutory requirements.

8.2.3 Monitoring and measurement of processes

Newhart Products applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, the organization:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

The process for determining and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (MP-824) and Management Responsibility procedures (AP-500).

8.2.4 Monitoring and measurement of product

Newhart Products monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes (MP-824).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product for delivery to the customer. Product release does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

When key characteristics have been identified, they are monitored and controlled.

When Newhart Products uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use. The plan precludes the acceptance of lots whose samples have known nonconformities. When required, the plan is submitted for customer approval.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- A record of the measurement results, and
- Type of measurement instruments required.
- Test records shall show actual test results data when required by specification or acceptance test plan.
- Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements. (Form F-824-002 Inspection Report)

8.2.4.2 First Article Inspection

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part as required, or following any subsequent change that invalidates the previous first article inspection result.

8.3 Control of Nonconforming Product

Newhart Products ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (QP-830).

The term "nonconforming product" includes nonconforming product returned from a customer.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

The organization does not use dispositions of use-as-is or repair, unless specifically authorized by the customer.

Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

In addition to any contractual, statutory or regulatory authority reporting requirements, Newhart Products system provides for timely reporting of delivered nonconforming product. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

8.4 Analysis of Data

Newhart Products determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (AP-500). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual improvement

Newhart Products continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

Newhart Products takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP-852) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,

- Records of the results of action taken (see 4.2.4), and
- Reviewing the effectiveness of the corrective action taken.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive action

Newhart Products determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (QP-853) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing the effectiveness of the preventive action taken

Related Documents

Management Responsibility AP-500

Customer Related Processes SP-720

Monitoring, Measuring and Analysis of Customer Satisfaction AP-821

Internal Audits QP-822

Monitoring and Measuring of Product and Realization Processes MP-824

Control of Nonconforming Product QP-830

Corrective Action QP-852

Preventive Action QP-853

Statistical Techniques QP-840

QUALITY SYSTEM MANUAL REVISIONS

Revision Level	Revision Date	Section	Description or Change
Original	05/10/2008	All	Re-issue to incorporate AS9100 REV B and ISO 9001:2000 requirements.
Rev. A	05/12/2010	All	Revised for clarification of AS9100 Rev B requirements and to incorporate changes required for ISO 9001:2008