
# AS 9100 Quality Systems Manual

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

**Revision F**

# 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 C 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 C. 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, Statutory and Regulatory Agencies via the Company Website:

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

# QUALITY POLICY

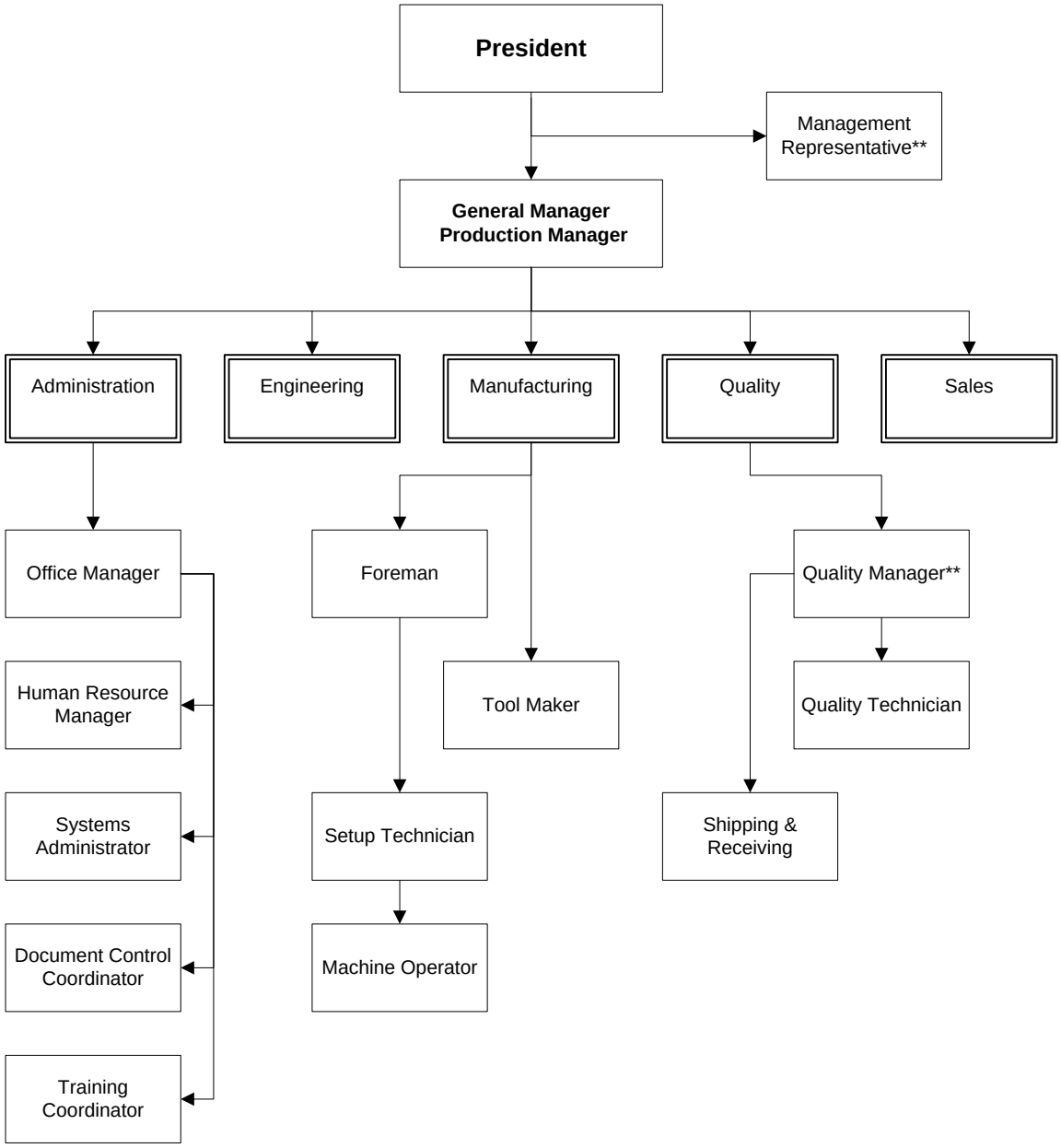
**Newhart Products will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue ever improving quality through programs that enable each employee to do their job right the first time and every time.**

President: *Thomas N. D'Aulizio*

*Thomas N. D'Aulizio*

The President of Newhart Products has formulated the quality policy. The policy is explained and discussed at the general orientation training given to all new employees and has been reviewed with all current employees. All employees are expected to know what the quality policy means to them as it affects their job or position within the company. The policy is posted in prominent locations throughout the facility.

QP 5.3




** Unless otherwise specified, the Quality Manager shall serve as Management Representative.

# 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. C.

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.

# Section 2: Normative Reference

## 2.0 Quality Management System References

The following document was used during the preparation of the Quality Management System:

- ISO9000:2005

## 3.0 Definitions

3.1 Risk – An undersirable situation that has both a likelihood of occurring and a potentially negative consequence.

3.2 Special Requirements – Those requirements identifed by the customer, or determined by the organization, which have high risks to beign achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requiremetns imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

3.3 Critical Items – Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of product; including safety, performance, form, fit, function, producibility, service life, etc.; that requiree specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.)

3.4 Key Characteristic – An attribure or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

# 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 Quality Management System shall also address customer and applicable statutory and regulatory quality management system requirements. 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.
- When Newhart outsources any process that affects product conformity to requirements, such processes are controlled to the extent required.

Reference: Turtle Diagrams

| | |
|---|---|
| Management Review Worksheet | QF 5.6-1 |
| Purchasing | QP 7.4 |

## 4.2 Documentation Requirements

### 4.2.1 General

The QMS documentation includes:

- A documented Quality Policy and Quality Objectives.
- This Quality Manual
- Documented Procedures and records
- Documents identified as necessary for the effective planning, operation and control of our processes

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

### 4.2.3 Control of Documents

All of the QMS documents are controlled according to the Document Control Procedure (QP 4.2.3). 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 hard copies and electronic copies 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

Reference: Document Control QP 4.2.3

### 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 and controlled according to the Control of Records Procedure (QP 4.2.4). 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.

The documented procedure also includes the method for controlling records that are created by and/or retained by the supplier.

Reference: Control of Quality Records QP 7.4

Control of Records QP 4.2.4

# INTERACTION OF PROCESSES

| Input | | Process | | Output |
|---|---|---|---|---|
| CUSTOMER<br>DRAWINGS & SPECIFICATIONS, RFQ, PO, | 1 | **ORDER PROCESSING**<br>QP 7.2, 7.2-1 | → | QUOTATION, PO,<br>PLANNING SHEET |
| PLANNING SHEET<br>AND<br>CUSTOMER DOCUMENTS | 2 | **ENGINEERING**<br>QP 7.1.2, QP 7.5 | → | PREPARE JOB FOLDER,<br>PURCHASING AND MANUFACTURING<br>REQUIREMENTS |
| SELECTION OF APPROVED SOURCES | 3 | **PURCHASING/RECEIVING**<br>QP 7.4, 7.5.3, 7.5.4, 8.2.4 | → | SUPPLIER PO<br>AND<br>VERIFICATION |
| PERSONNEL<br>TRAINING<br>EQUIPMENT | 4 | **RESOURCES**<br>QP 6.2.2, 6.3,7.5.1 | | BUSINESS ADMINISTRATION<br>PRODUCT MANUFACTURING |
| QUALITY POLICY<br>QUALITY MANUAL<br>MANAGEMENT RESPONSIBILITY<br>ANALYSIS OF DATA<br>CUSTOMER FEEDBACK | 5 | **QUALITY MANAGEMENT SYSTEM**<br>QP 4.2.3,4.2.4, 5.0, 5.3, 7.0,7.2 8.2.1, 8.2.4 | | CORRECTIVE ACTION<br>PREVENTIVE ACTIONS<br>CUSTOMER SATISFACTION |
| SHOP TRAVELER, DRAWINGS, FORMS | 6 | **MANUFACTURING**<br>QP 6.3, 7.0,7.5.1, 7.5.3, 7.6, 8.2.4, 8.3 | → | FINISHED PRODUCT STATUS AND<br>SIGN OFFS |
| TRAVELER, PACKING SLIP,<br>CERTS | 7 | **INSPECTION**<br>QP 8.2.4, 7.6 | → | INSPECTION SIGN OFFS AND<br>AUTHORITY TO SHIP |
| PACKING SLIP, CERTS, CUSTOMER DOCUMENTATION | 8 | **PACKAGING AND SHIPPING**<br>QP 7.5.5 | → | SIGNED RECEIVER FROM CUSTOMER OR SHIPPER |
| SURVEYS,<br>CUSTOMER REPORTS,REJECTIONS,<br>COMPLAINTS | 9 | **CUSTOMER FEEDBACK AND MANAGEMENT REVIEW**<br>QP 4.2.3, 4.2.4, 5.0, 8.2.1, 8.5., 8.2.2 | → | CORRECTIVE AND PREVENTIVE<br>ACTIONS AS NECESSARY,<br>MANAGEMENT REVIEW MINUTES |

# 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 does the following:

- Communicate the importance of meeting customer, statutory, and regulatory requirements to the organization.
- 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 will ensure that customer requirements are met with the aim of ensuring customer satisfaction.

Newhart Products will ensure that product conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not or will not be achieved. 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 (QP 7.2).

Reference: Management Review Worksheet QF 5.6 -1

## 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 QP 5.3.

## 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.

Reference: Management Review Worksheet QF 5.6-1

### 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 REV C 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.

Reference: Newhart Organization Chart

### 5.5.2 Management Representative

Unless otherwise specified, the Quality Manager shall serve as the Management Representative, having the 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 and unrestricted access to top management to resolve matters pertaining to quality management.

Reference: Newhart Organization chart

### 5.5.3 Internal Communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS includes 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 at management review meetings a minimum of once per year. 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.

Reference: Management Review Worksheet QF 5.6-1

### 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
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the quality management system
- Recommendations for improvement
- Quality Policy Resources

  Reference QF 5.6-1

### 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

Reference: QF 5.6-1

QP 5.0

# Section 6

# Resource Management

## 6.1 Provision of Resources

To effectively maintain and continually improve the system, management determines and provides necessary resources.

Reference: Management Review Worksheet QF 5.6-1

## 6.2 Human resources

### 6.2.1 General

To ensure competence of our personnel, positions are filled based upon matching the skills and qualifications of the individual with the required qualifications necessary to perform the job. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with applicable training, provide the competence required for each position.

Reference: QF 6.2.2-1

E2 Quality Module, Employee Training Record

### 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
- Maintains appropriate records of education, training, skills and experience

Reference: QP 6.2.2

E2 Quality Module, Employee Training Record

### 6.3 Infrastructure

To meet quality objectives and product requirements Newhart Products has determined the infrastructure needed (QP 6.3). 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.

Reference: Infrastructure QP 6.3

Management Review Worksheet QF 5.6-1

## 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.

# Section 7

# Product Realization

## 7.1 Planning of Product Realization

Newhart Products plans and develops the processes needed for product realization. Planning of these realization processes is consistent with the other requirements of the Newhart Management System. In planning the processes for realization of product, Newhart has determined the following, as appropriate:

a) Quality objectives and requirements for the product, section 5.4.1; This includes consideration of aspects such as product and personal safety
b) Suitability of parts and materials used in the product
c) Reliability/availability/maintainability, producibility and inspect-ability,
d) The need to establish processes and documentation, and to provide resources specific to the product, section 6.1;
c) Verification, validation, monitoring, measurement, inspection and test activities, specific to the product and the criteria for product acceptance;
d) The records needed to provide that the realization of the processes and resulting product meet requirements.
e) Configuration management as appropriate to the product and operations
f) Resources to support the use and maintenance of the product

**Note: 1. Documentation** that describes how the processes and resources of the quality management system are applied for a specific product are referred to as a Quality plan. (e.g. process description).
**Note: 2** Newhart has applied the requirements to the Product Realization process.

Reference: QF 8.2.4-1 Inspection report
QSM Process Flow Chart
QF 5.6-1 Management Review Worksheet
QSM 7.1.3 Configuration Management
QF 7.1-1 Quality Planning Operation Sequence Sheet

### 7.1.1 Project Management:

Newhart Products plans and manages product realization in a structured and controlled manner to meet the requirements of risk, within resource and schedule constraints. Each order is considered a project and is managed by the President and General Manager.

### 7.1.2 Risk Management:

Newhart Products has established, implemented, and maintains a process for managing

risk as follows:

a) Responsibilities are assigned
b) Risk criteria is defined
c) Includes identification, assessment, and communication throughout the product realization process.
d) Identifies and implements management actions to mitigate risks throughout the product realization process.
e) Acceptance of risks after implementation of mitigating actions.

Reference: QP 7.1.2 Risk Management

### 7.1.3 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.

Reference: Configuration Management, QP 7.1.3

| | |
|---|---|
| Quality Planning/Operation Sequence Sheet | QF 7.1-1 |
| Contract Review Planning Sheet | QF 7.1-2 |

### 7.1.4 Control of Work Transfers

Newhart has established, implemented, and maintains a process to plan and control the temporary or permanent transfer of work (e.g. , from one of our facilities to another, from Newhart to a supplier, from one of our suppliers to another, and, to verify the conformity of the work to requirements.

Reference: Purchasing QP 7.4

## 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 or intended use if known.
- Statutory and regulatory requirements applicable to the product,
- Additional requirements considered necessary by Newhart Products

Reference: Customer Related Processes QP 7.2

### 7.2.2 Review of Requirements Related to the Product

Newhart Products reviews requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined, including any special requirements
- 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 have been (i.e. new technology, short delivery time frame) identified.
- Reference: Customer Related Processes QP 7.2

### 7.2.3 Customer Communication

Newhart Products has implemented an effective procedure (QP 7.2) for communicating with customers in relation to:

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

QP 8.3 Control of Non Conforming Product
QP 8.5.2 Corrective Action
QSM 8.2.1 Customer Satisfaction
QP 7.2 Customer Related Processes

## 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 C section 7.3, Design and Development do not apply to Newhart Products operation and have been excluded from our quality management system.

## 7.4 Purchasing

### 7.4.1 Purchasing Process

A documented procedure (QP 7.4) 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.

An approved supplier list is maintained which includes the approval status and scope of approval.

Where required both the organization and suppliers use customer-approved special process sources.

The process, responsibilities and authority for the approval status decision, and conditions for a controlled use of suppliers depending on the supplier's approval status, along with determination of and management of the risk when selecting and using suppliers, is documented in procedure QP 7.4.

Reference: QP 7.4 Purchasing
E2 Approved Supplier List
QP 7.1.2 Risk Management

### 7.4.2 Purchasing Information

Purchasing documents contain information describing the product to be purchased, including where appropriate:

a) Requirements for approval of product, procedures, processes, and equipment
b) Requirements for qualification of personnel
c) Quality management system requirements
d) Identification the revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data.
e) Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by Newhart Products, and as applicable critical items including key characteristics.
f) Requirements for test specimens for design approval,

inspection/verification, investigation, or auditing.

g) Requirements regarding the need for the supplier to

- notify Newhart Products of non-conforming product disposition,
- obtain Newhart Products approval for non-conforming product disposition,
- notify Newhart Products of changes in product and/or process, changes of suppliers, changes of manufacturing facility location, and where required, obtain Newhart Products approval.
- Flow down applicable requirements, including customer requirements

h) records retention requirements

i) right of access by the Newhart Products, our customers, and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

Newhart Products ensures the adequacy of specified requirements contained in the purchasing documents prior to their release.

Reference:

QP 7.4 Purchasing
QP 7.4.2 Purchase Order Provisions

### 7.4.3 Verification of Purchased Product

Newhart Inc. identifies and implements plans and the activities necessary for verification of purchased product. Where Newhart Inc. or its customer proposes to perform verification activities at the supplier's premises, we specify the intended verification arrangements and method of product release in the purchasing information.

Customer verification activities performed at any level of the supply chain will not be used by Newhart Products or the supplier as evidence of effective control of quality and does not absolve Newhart Products of our responsibility to provide acceptable product and comply with all requirements.

Verification activities can include obtaining objective evidence, inspection and audit at the suppliers premise, review of required documentation, inspection of products upon receipt, or supplier certification.

When purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is

subsequently found that the product does not meet requirements.

If Newhart Products chooses to delegate verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations made. The arrangements and method of product release will be stated in the purchasing information.

Reference: QP 7.4 Purchasing
QF 7.4-2 Purchase Order Provisions

## 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 (QP 7.5.1). 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).
- Clearly defined criteria for workmanship

Reference:

QSM Interaction of Processes Chart

QW 7.5.1 Workmanship Standards

QP 7.5 Control of production provision

QP 7.6 Control of Monitoring and Measurement Equipment

QP 7.1.2 Risk Management

### 7.5.1.1 Production Process Verification

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.
- First Article Inspections are performed on a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result, such as process, tooling or engineering changes, or per customer requirement.

Reference: Monitoring and Measuring of Product and Realization Processes QP 8.2.4

### 7.5.1.2 Control of Production Process Changes:

Authorized people for approving changes to production processes are identified in the Procedure QP 7.5.1. 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.

Reference: QP 7.5 Control of Production Provision

### 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 be established for production equipment or tooling in storage.

### 7.5.1.4 Post Delivery Support

Reference: QP 8.3-Control of Non-Conforming Product
QP 8.5.2 Corrective Action
QP 8.5.3 Preventive Action

### 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 (QP 7.5.3).

- 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

Reference: QP 7.5.3 Identification and Traceability

### 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 (QP 7.5.4) 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 (QP 7.5.5). 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.

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

Reference: QP 7.5.5 Preservation of Product

## 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 7.6) 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.

Reference QP 7.6 Control of Monitoring and Measuring Devices

# 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.

Reference: Entire QMS and QP 8.2.2 Internal Audits

## 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. Information to be monitored and used for the evaluation of customer satisfaction includes, but not limited to, product conformity, on-time delivery performance, customer complaints, and corrective action requests. A customer satisfaction plan for customer satisfaction improvement that addresses deficiencies identified by these evaluation, and assess the effectiveness of the results, is documented. The method for obtaining and using this information is identified in the Customer Related Processes (QP 7.2) and the Management Responsibility procedures (QP-5.0).

References: QF 5.6-1 Management Review Worksheet
QP 5.0 Management Responsibility
QP 7.2 Customer Related Processes

### 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 8.2.2).

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.

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

Reference QP 8.2.2 Internal Audits

### 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
- Determines if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, 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 (QP 8.2.4) and Management Responsibility procedures (QP-5.0).

Reference: QP 8.2.4 Monitoring and Measuring of Product Realization Processes

QP 5.0 Management Responsibility

QP 8.2.2 Process diagrams and PEARS

### 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 (QP 8.2.4).

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 critical items, including 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.

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. (QF 8.2.4-1 Inspection Report)
- Newhart ensures that all documents required to accompany the product are present at delivery.

## 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 Non-conforming Product procedure (QP 8.3).

The term “non-conforming product” includes non-conforming 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.

Additional action is taken necessary to contain the effect of the nonconformity on other processes or products.

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.

References: QP 8.3 Control of Non-Conforming Product

## 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

References: QP 5.0 Management Responsibility
QF 5.6-1 Management Review Minutes

## 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. Newhart monitors the implementation of improvement activities and evaluates the effectiveness of the results.

References: QF 5.6-1 Management Review Minutes

### 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 8.5.2) 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,
- Specific actions where timely and/or effective corrective actions are not achieved, and
- Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

References: QP 8.5.2 Corrective Action

### 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 8.5.3) 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

References: QP 8.5.3 Preventive Action

# 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 |
| Rev B | 06/20/2011 | All | Revised to incorporate changes required for AS9100 REV C |
| -- | 09/19/2011 | 4.2.3 | Added "…to hard copies and electronic copies…" |
| Rev C | 07/16/2012 | 1.2 | Removed reference to 7.5.2., and 7.5.1.4 exclusion. |
| " | " | 3.0 | Added definitions. |
| " | " | 4.1 | Added reference to Turtle Diagrams. |
| " | " | 7.1.3 | Added 'Configuration Management, QP 7.1.3. |
| " | " | 7.2.2 | Added risk examples. |
| " | " | 7.4.1 | Expanded to ref. approved Supplier List, Cust. Approved Special Process, QP 7.4 |
| " | " | 7.5.1.4 | Added reference to QP 8.3 Control of Non Conforming Product |
| " | " | 8.2.1 | Added info on monitored information, improving customer satisfaction, assessing effectiveness. |
| " | " | 8.2.2 | Removed section on tools/techniques. |
| " | " | 8.2.3 | Added "Determines if the process…". |
| " | " | 8.2.4 | Added "Critical Items", "Newhart ensures…". |
| " | " | 8.3 | Added "Additional action…". |
| " | " | 8.5.1 | Added "Newhart monitors…". |
| " | " | 8.5.2 | Added "Determining if additional….". |
| REV D | 06/16/15 | 1.2 | Removed 7.5.1.4 Post-Delivery Support exclusion reference. |
| REV E | 06/24/15 | PG. 12 | Added 'Resources' and 'Quality Management Systems' Processes to Interaction of Processes diagram. |
| REV F | 11/19/15 | PG. 12 | Added 'Training' to 'Resources' Process. |