

WIDGET WORKS COMPANY, INC

Quality System Manual

ISO 9000

This quality manual has been reviewed and approved for use. Individual section revisions may be made from time to time as required with all such revisions controlled.

President

Date

Management Representative

Date

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Quantum Associates, Inc

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Distribution

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Authorized Holder

Management Representative
President
Vice President of Administration
Operations Manager

Quantum Associates, Inc

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1.0 Scope and Introduction

1.1 General

Widget Works Company, Inc is located at 344 Revere Drive, Northbrook, Illinois. Widget Works Company is involved in the manufacture of custom carbide saws, knives, and special tooling and accessories for various applications.

Widget Works Company, Inc developed and implemented a quality management system to better satisfy the needs of its customers and to improve management of the company. The quality system complies with the international standard ISO 9001:2008.

The manual is divided into five sections corresponding to the quality system requirements of ISO 9001:2008. The purpose of this manual is to define and describe the quality system, to define the authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present our quality system to our customers and to inform them what specific controls are implemented to assure product quality.

1.2 Application

Widget Works Company has determined that the following requirements are not applicable to the operations of the company and are documented as exclusions.

Exclusion: ISO 9001:2008 Section 7.3, Design and/or Development, including all subsections

Justification: Widget Works Company, Inc does not design or develop products. The customers specify all principal product characteristics by providing drawings to Widget Works. Our activities are limited to developing methods and means of production and fabrication of carbide tools.

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2.0 Normative References

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

- American National Standard ANSI/ISO/ASQ Q9000-2005, Quality Management Systems FunWidget Workstal and Vocabulary
- American National Standard ANSI/ISO/ASQ Q9001-2008, Quality Management Systems—Requirements

3.0 Quality Management Systems Definitions

- Customer owned property—any type of instrumentation, prints, drawings accessories, or manuals that belong to a customer.
- Customer supplied product— any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Product—the end result of meeting all contract terms and conditions for manufactured product.
- 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.

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4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Widget Works Company has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008. 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.

No changes may be made to this manual unless approved by the Management Representative or an authorized representative.

Widget Works Company has established, documented, implemented, maintained and is continually improving its Quality Management System in accordance with the requirements of the ISO 9001:2008 standard. In order to implement the Quality Management Widget Works Company has:

- Determined the processes needed for the Quality Management System and their application throughout the organization and documented them on the deployment flowchart at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes and illustrated them on the flowchart
- Determined criteria and methods needed to ensure that the operation and control of processes are effective
- Ensured the availability of resources and information necessary to support the operation and monitoring of these processes
- Established systems to monitor, measure, and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

Widget Works Tool Co. has established the following documentation for its quality management system.

- Quality Policy and Quality Objectives
- This Quality Management System Manual
- Documented Procedures referenced in the text of this Quality Systems Manual
- Planning, operation and process control documents such as:

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- Work Instructions (if used)
- Records of Internal Reviews
- Inspection & Test Reports (if prepared)
- Internal/External Audit Reports & Corrective Action
- Other documents used to ensure effective planning
- Operation and Control Records

4.2.2 Quality Manual

Widget Works Company has established and maintained a Quality Management System Manual. The scope and permissible exclusions of the QMS are described in section one of this manual. It references documented procedures governing work activities. It includes a description of sequences and interaction of processes, which fall under the scope of the Quality Management System. The Quality Manual is a controlled document. The Management Representative is responsible to ensure the initial issue and subsequent changes are acknowledged by those authorized to receive the QMSM.

4.2.3 Control of Documents

Documents required by the quality management system are controlled by documented procedures, which provide for the:

- Approval of documents for adequacy prior to being issued,
- Review and update as necessary and re-approval,
- Ensure that changes and the current revision status of documents are identified,
- Ensure that relevant versions of applicable documents are available at points of use,
- Ensure that documents remain legible and readily identifiable,
- Ensure that documents of external origin determined by Widget Works Carbide Tool to be necessary for the planning and operation of the quality management system are identified and their distribution is controlled,
- Prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Quality Records

Quality records established to provide evidence of conformity to requirements and of the effective operation of the quality management system are controlled. The records are maintained according to the Control of Quality Records Procedure. The procedure defines the controls needed for identification, storage, protection, retrieval, retention and disposition of quality records.

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Related Procedures

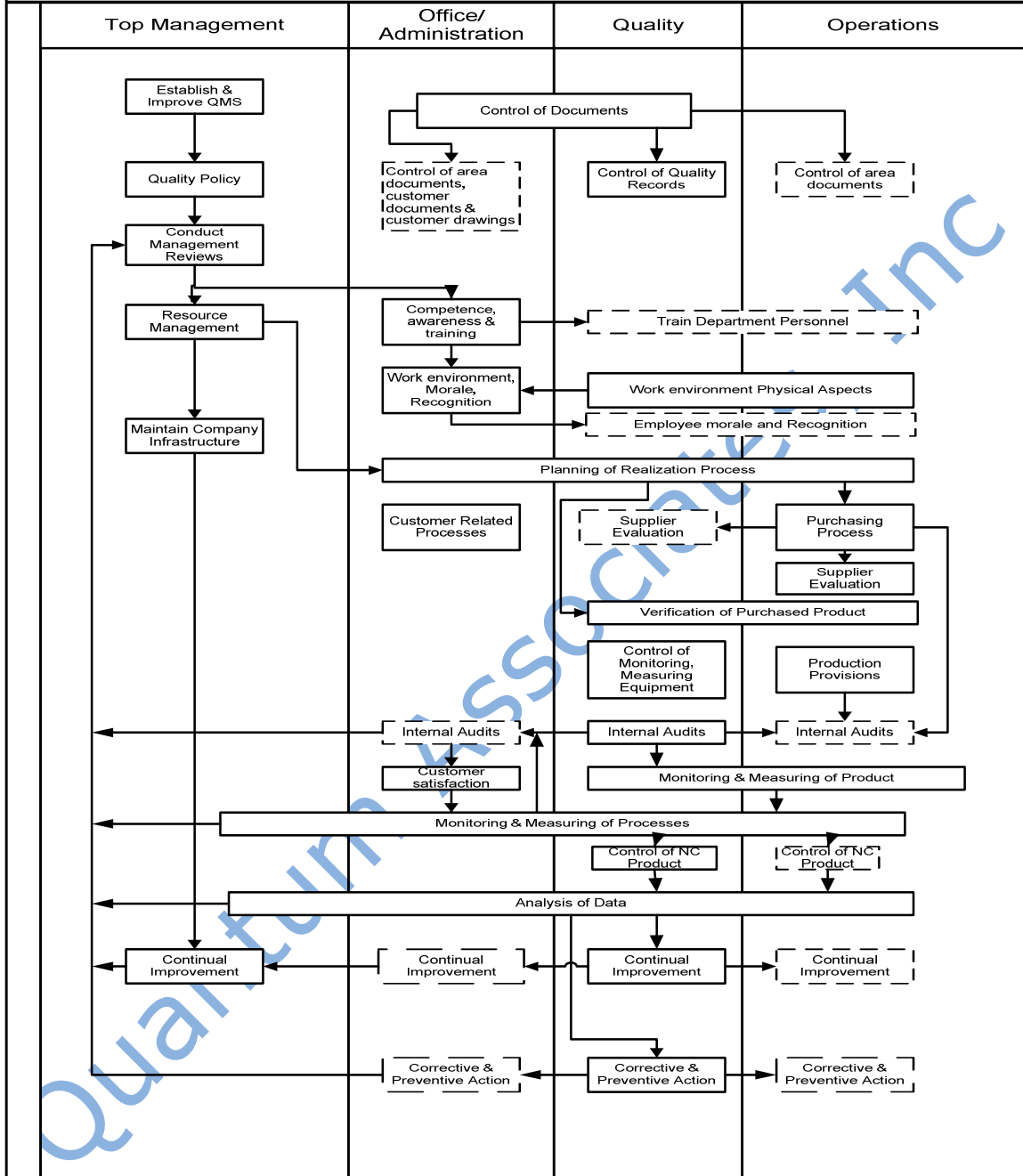
SOP – 423 Document Control

SOP – 424 Control of Quality Records

Interaction of Processes

Quantum Associates, Inc

Interaction of Processes- Damen Carbide Tool



Legend:
 Solid line = Primary Responsibility
 Dotted line = Secondary Responsibility

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5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

The top management of Widget Works Company is committed to the development and improvement of the Quality Management system by:

- Communicating the importance of meeting customer, regulatory and legal requirements
- Establishing annual quality objectives
- Establishing the quality policy
- Conducting management reviews in accordance with Paragraph 2.6 of this QMS.
- Ensuring the availability of necessary resources in accordance with Section 3.0 of this QMS.

5.2 Customer Focus

Widget Works Company strives to identify 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.

5.3 Quality Policy

Top management has established the following quality policy.

Widget Works Company is committed to understanding and meeting the needs of our customers. It is the responsibility of all employees to achieve continuous improvement in all aspects of our business to deliver the highest quality products and services.

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.

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5.4 Planning

5.4.1 Quality Objectives

Top Management of Widget Works Company has identified the following Quality Objectives. The objectives are measurable, consistent with policy; relevant to the successful completion of construction projects; established at relevant functions and levels within Widget Works Company and are measurable and consistent with the quality policy including the commitment to continual improvement.

Our main objectives are:

- 1. Customer satisfaction measured by on time deliveries and customer returns.**
- 2. In-house acceptance measured by number of parts rejected through our quality control.**
- 3. Zero lost time accidents as measured by the number of hours of sustained operation without lost workdays as a result of an accident.**

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 ISO 9001 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 interrelationship 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 organization 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 organization chart is located at the end of this section.

5.5.2 Management Representative

Widget Works Company has assigned The Vice President of Administration as the Management Representative for Quality. He/she shall ensure the Quality system is established, maintained, and implemented and shall report to top management quarterly and make recommendations for Quality System improvements. Reports shall be issued in writing to top management and maintained in an open status until the resolution of

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outstanding items. The management representative shall assure that everyone in the company is aware of customer requirements.

5.5.3 Internal Communication

The Company ensures the processes of the Quality Management System and their effectiveness are communicated throughout the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, Internal Audit Closing meetings, and other routine business communications.

5.6 Management Review

5.6.1 General

Widget Works Company's top management shall review the Quality Management System at least once a year and more often as needs dictate to ensure its suitability, adequacy and effectiveness. The Quality Management System, quality policy and quality objectives will be evaluated for any needed change. Records of these reviews shall be maintained.

5.6.2 Review Input

Management Reviews shall utilize:

- Internal and external Quality Audit results
- Customer performance evaluations (feedback)
- Process performance and product conformance results
- Preventive and corrective action status
- Follow up on actions from previous Management Reviews
- Other changes (i.e. business climate, scope of work changes, etc) that could affect the Quality Management System

5.6.3 Review Output

Results of Management Reviews shall be recorded and address as appropriate

- Improvements in the Quality Management System and its processes
- Improvements in product related to customer requirements
- Resource needs

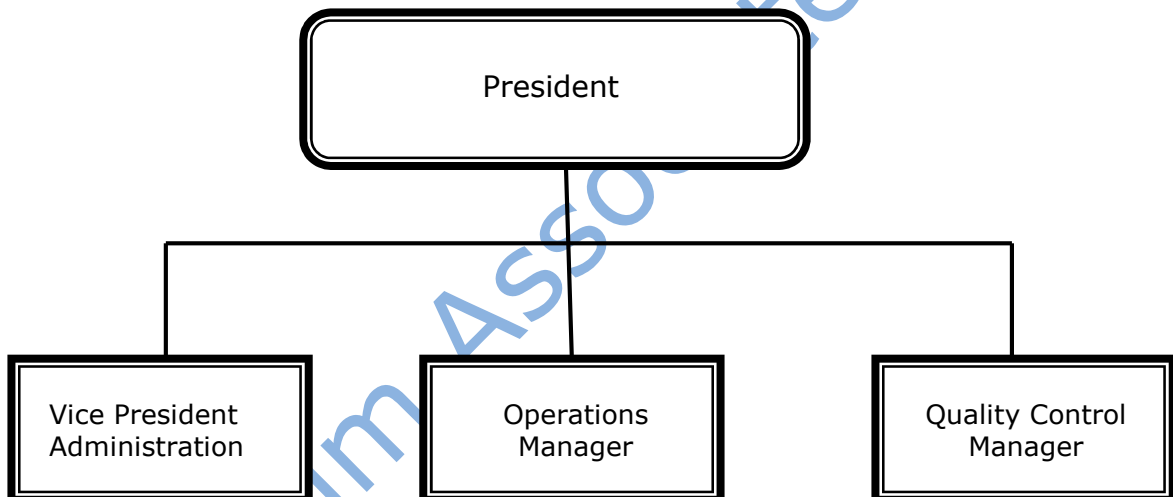
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Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of the management review.

Related Procedures

- SOP – 560 Management Responsibility
- SOP – 720 Customer Related Processes

Widget Works Company Organization



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6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Widget Works Company has implemented a Quality Management System that complies with the ISO 9000:2008 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 necessary resources and provides those resources.

6.2 Human Resources

6.2.1 General

Widget Works Company shall assign personnel to work affecting conformity to product requirements that are competent on the basis of appropriate education, training, skills and experience. The Operations Manager is responsible for reviewing the work order to determine any customer requirements for competency of personnel.

6.2.2 Competence, Training and Awareness

Widget Works Company shall:

- Determine the necessary competency needs for personnel performing work affecting conformity to product requirements. Widget Works Company has developed position descriptions for those personnel performing work affecting conformity to product requirements, which identify necessary competencies. Human Resources maintains the latest issue of such position descriptions
- Provide training to satisfy competency needs. The Operations Manager is responsible to identify training needs of manufacturing personnel and assure training is performed. Department Managers are responsible for training department personnel.
- Evaluate the effectiveness of the training provided.
- Ensure employees are aware of how their work activities contribute to the achievement of quality objectives.
- Maintain records of education, training skills and experience. The Vice President of Administration is responsible to ensure appropriate records including records of training activities and the subject matter of the training are maintained.

6.3 Infrastructure

To meet quality objectives and product requirements Widget Works Company has determined the infrastructure needed. The infrastructure has been provided and includes

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buildings, workspace, process equipment, utilities and supporting services (such as transport, communication and information systems). As new infrastructure requirements arise they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity.

6.4 Work Environment

Widget Works Company has identified and is managing the physical, environmental, and other factors (such as noise, temperature and humidity, lighting or weather) of the work environment needed to assure work output is acceptable.

Related Documents

SOP – 622 Competence, Awareness and Training

SOP – 630 - Infrastructure

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

In planning the processes of realization of product the following is determined, as appropriate:

- The quality objectives and requirements for the product,
- Processes, documentation and resources specific to the product
- Verification, validation, monitoring, measurement, inspection and test activities specific to the product
- Criteria for product acceptance.

The output of quality planning includes documented quality plans, processes, and procedures.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Widget Works Company determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities

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- 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 Widget Works Company

Customer requirements are determined according to the Customer Related Processes Procedure.

7.2.2 Review of Requirements Related to the Product

Widget Works Company has a process in place for the review of requirements related to the product. 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
- Widget Works Company 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, Widget Works communicates changes to relevant personnel and amends relevant documents

7.2.3 Customer Communication

Widget Works Company has implemented an effective process 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

This section is excluded. Widget Works Company does not design product. Customers submit prints defining their specifications.

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7.4 Purchasing

7.4.1 Purchasing Process

A documented procedure 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.

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

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 describes the process used to verify that purchased product meets specified purchase requirements. If Widget Works Company 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.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Widget Works Company plans and carries out production and service provision under controlled conditions. 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

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7.5.2 Validation of Processes for Production and Service Provision

Widget Works Company validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, and 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.

Widget Works Company has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

7.5.3 Identification and Traceability

Widget Works Company identifies the product status throughout product realization according to the Identification and Traceability procedure. Product is identified with respect to monitoring and measurement requirements.

Widget Works Company controls the unique identification of the product where ever traceability is a specified requirement and maintains records.

7.5.4 Customer Property

Widget Works Company exercises care with customer property while it is under the organization's control or being used. A procedure outlines the Identification, verification, protection and safeguarding of customer 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

Widget Works Company preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

Widget Works Company has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure 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.

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Where necessary to ensure valid results, measuring equipment is:

- Calibrated, verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards
- 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.

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

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

Related Documents

SOP- 710 Planning of Product Realization Processes

SOP- 720 Customer Related Processes

SOP – 740 Purchasing

SOP – 750 Control of Production and Service Provision

SOP – 753 Identification and Traceability

SOP – 755 Preservation of Product

SOP – 760 Control of Monitoring and Measuring Devices

8.0 Measurement, Analysis and Improvement

8.1 General

Widget Works Company has planned and implemented the monitoring, measurement, analysis and improvement processes 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.

This process is identified in documented procedures and includes determination of applicable methods, including statistical techniques, and the extent of their use.

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8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Widget Works Company 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 and the Management Responsibility procedures.

8.2.2 Internal Audit

Widget Works Company conduct 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 and 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 results and maintaining are defined and documented in the Internal Audit procedure.

To ensure objectivity and impartiality auditors are never selected or assigned to audit their own work or areas under their control.

The management responsible for the area being audited is responsible for ensuring that any necessary corrections or 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.

8.2.3 Monitoring and Measurement of Processes

Widget Works Company 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. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring of Measurement of Processes and Management Responsibility procedures.

8.2.4 Monitoring and Measurement of Product

Widget Works Company monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at

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appropriate stages of the product realization process identified in the Monitoring and Measuring of Product procedure.

Records indicate the person(s) authorizing release of product for delivery to the customer. Product release and service delivery to the customer 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.

8.3 Control of Nonconforming Product

Widget Works Company 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.

8.4 Analysis of Data

Widget Works Company determines, collects and analyzes 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. 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
- Conformity to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

Widget Works Company 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.

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8.5.2 Corrective Action

Widget Works Company takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure 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.

8.5.3 Preventive Action

Widget Works Company 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 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

SOP – 560 Management Responsibility

SOP – 720 Customer Related Processes

SOP – 821 Monitoring, Measuring and Analysis of Customer Satisfaction

SOP – 822 Internal Audits

SOP – 823 Measuring, Monitoring and Analysis of QMS Processes

SOP – 824 Monitoring and Measuring of Product and Realization Processes

SOP – 830 Control of Nonconforming Product

SOP – 852 Corrective Action

SOP – 853 Preventive Action