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# Quality System Manual

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## 1 About this Manual

This manual was developed and is maintained by the Management Representative for the quality management system. Requests for changes should be submitted to the Management Representative. Updates of the manual are issued as required. A copy of this quality manual is kept with each department head who ensures that it is easily accessible to all employees.

It is the responsibility of the department heads to ensure that all employees are familiar with the content of the quality manual and that they are kept informed of any changes and updates.

The department heads ensure that obsolete issues or pages of this manual are invalidated and/or disposed of as per established procedure. "Appendix B" shows current revision levels of revised pages and a brief description of the change. In case of doubt, the current issue date or revision number shall be confirmed with the Management Representative.

For each clause, reference is made to the applicable quality assurance procedure (QAP), which again makes reference to other pertinent procedures or work instructions. QMS interactive processes are described in "Appendix A". This manual and the quality management system procedures should be used as cross-reference for document review and auditing.

### 1.1 Distribution:

Copy No.	Location	Distribution
No. 1	Office	Tom Selnau
No. 2	Inspection	Patrick Jablonski
No. 3	Fourslide, Coilers, Torsion	Ed Pardo
No. 4	Shipping & Receiving	Mark Tryon
No. 5	Secondary, Heat Treat, Grind	John West
No. 6	LRQA	N/A

### 1.2 Approvals

**This edition of the Quality Manual is effective as of June 25, 2003**

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**President:** Ed Selnau **Date:** June 25, 2003

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**Management Representative:** Patrick Jablonski **Date:** June 25, 2003

## 2 Introduction

**Arrow Manufacturing Company**, hereafter called **Arrow**, is located at 16 Jeannette Street, Bristol, Connecticut. Arrow 's business activities are the manufacture of flat, coil, compression, extension and torsion springs; flat metal and wire forming, according to customers' specifications.

This quality manual describes the quality management system of Arrow and its compliance with the requirements of **ISO 9001:2000**. Its purpose is

- **for internal use**, to communicate to all employees the company's quality policy and quality objectives, to make them familiar with the method of compliance with **ISO 9001:2000** requirements, to facilitate the implementation and maintenance of the quality management system and to ensure its continuity and required updates during changing circumstances, to provide effective communication and control of quality related activities and a documented base for quality system audits.
- **for external use**, to inform Arrow's customers and other interested external partners about Arrow's quality policy, its implemented quality management system and measures of compliance with **ISO 9001:2000** requirements.

## 3 General

### 3.1 Scope

The quality management system described hereafter complies with the requirements of **ISO 9001 Revision 2000** and covers the manufacture of flat, coil, compression, extension and torsion springs; flat metal and wire forming, according to customers' specifications.

3.1.1 Application exclusion: Requirements documented under clause 7.3, Design & development are considered excluded from the scope of this QMS and do not affect the organizations ability, or responsibility, to provide product that meets our customer and/or regulatory requirements. Arrow Manufacturing Company does not provide design as a process of its QMS or for its manufactured product.

### 3.2 References

- **ISO 9000: 2000**, quality management systems - fundamentals and vocabulary
- **ISO 9001: 2000**, quality management systems - requirements
- **ISO 9004: 2000**, quality management systems - guidelines for performance improvement

## 4 Quality Management System

## **4.1 General Requirements** (*Management Review 4.1-1*)

The management of Arrow is committed to establish, document, implement, maintain and continually improve the quality management system in order to ensure that products and service meet specified requirements. This quality management system shall meet the requirements of ISO 9001: 2000.

To define how the requirements of the quality management system shall be met, as applicable and required, documented quality management system procedures, operating procedures, work instructions as well as other necessary documents shall be developed and available, in order to identify, define, control, verify, measure, monitor and analyze the various processes of the quality management system regarding their effective implementation, operation, compliance with ISO 9001:2000, results in relation to requirements and continual improvement. These documents shall be appropriate for Arrow's operation and the effective functioning and administration of the quality management system. The availability of required resources shall be ensured.

In the event that processes for the manufacture of product or technical services are outsourced to third party organizations, it shall be ensured that the necessary controls are identified, established and implemented in order to ensure conformity to requirements. Outsourcing of processes shall be identified in the applicable Quality Plan(s).

## **4.2 Documentation Requirements** (*Quality Planning 4.2-1*)

### **4.2.1 General** (*Quality Planning 4.2-1*)

It is the responsibility of the Management Representative for the quality management system to ensure that the documentation of the quality management system includes: quality policy, quality objectives, this quality manual, quality management system procedures covering the clauses 5.5.6, 5.5.7, 8.2.2, 8.3, 8.5.2 and 8.5.3, the necessary documents to ensure the effective planning, operation and control of the quality management system processes, and the records as required by ISO 9001:2000.

### **4.2.2 Quality Manual** (*Quality Planning 4.2-1*)

The Management Representative is responsible for the development and maintenance of the quality Manual. This quality manual shall outline the requirements of ISO 9001:2000, including any applicable permissible exclusions in scope and the justification of the exclusion. These exclusions shall be limited to requirements contained in clause 7 of the standard. The overall responsibilities and brief descriptions of the interaction of processes of the quality management system are included in the applicable paragraphs of this manual. More details on responsibilities and quality management system processes can be found in the referenced quality system procedure or operating procedure. Each clause in this manual shall be referenced to the applicable quality management system procedure (QMS) which again shall make reference to operating procedures and work instructions. These references should be used as cross-reference for document review and quality audits.

### **4.2.3 Control of Documents** (*Quality Manual Control 4.5-1, Production Document Control 4.5-2, External Document Control 4.5-3*)

It is the responsibility of the Management Representative to ensure that quality management system (QMSP) level procedures are established for the effective control of documents and data needed for the operation of the quality management system. Controlled documents shall be identified with the current revision status and changes made. Among other requirements, this procedure shall define: approval of documents and data, review, update and re-approval of documents and data, availability of current revisions, removal and/or invalidation and proper identification of obsolete documents and data which are retained for legal or reference purposes.

#### 4.2.4 Control of Records (*Quality Records 4.16-1, Quality Manual Control 4.5-1*)

It is the responsibility of the Management Representative to develop, document and implement a procedure for the control of records in order to demonstrate conformance to specified requirements and the effectiveness of the quality management system as well as compliance with statutory and regulatory requirements. This procedure shall specify how records shall be identified and stored in a suitable place and environment in order to ensure their availability and protection against deterioration. Retention time of these records shall be established and their disposal shall be defined and documented.

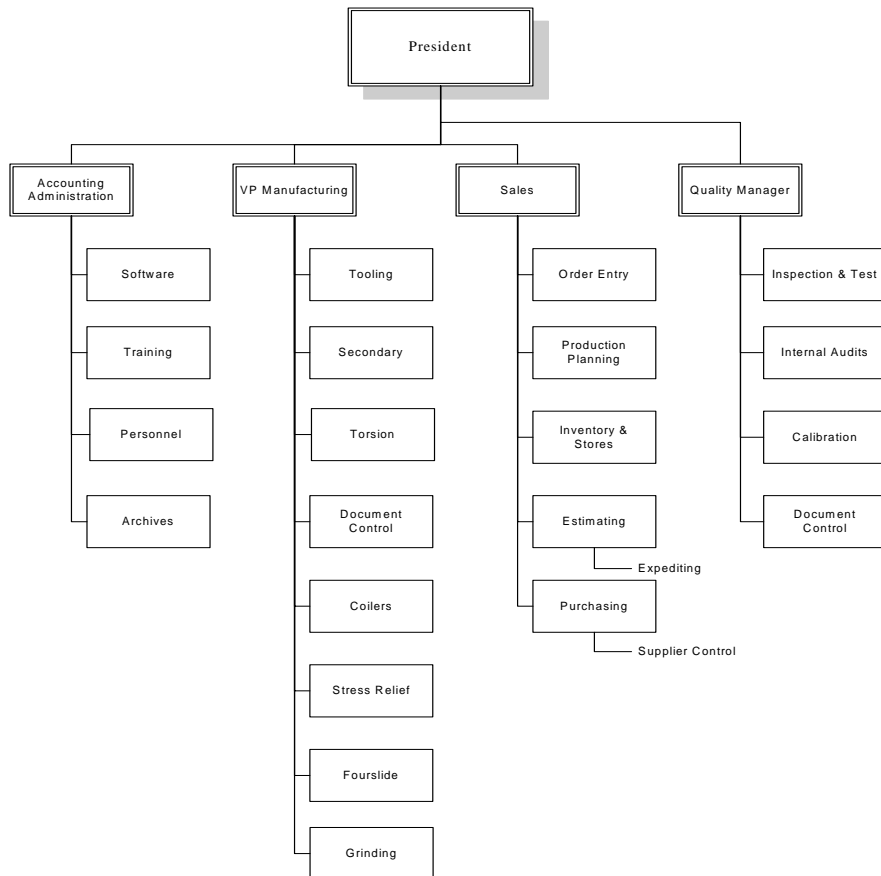
Master lists with current revision levels of controlled documents and data shall be issued by Management Review Committee (MRC) or its members. These master lists shall be readily available to all functions concerned. Documents and data shall be legible, readily identifiable and retrievable. As required, documents and data of external origin shall be identified and controlled. Records shall be controlled.

## 5 Management Responsibility

### 5.1 Management Commitment (*Management Review 4.1-1*)

In addition to other activities and issues related to quality, the highest level of management of Arrow shall ensure that procedures are implemented in order to make employees aware of the importance of meeting customer requirements, that a quality policy and quality objectives are established, that yearly management reviews of the performance of the quality management system are conducted and that required resources for the proper functioning of activities affecting quality and customer satisfaction are available. The proper implementation and functioning of the quality management system, as well as the continual improvement of its effectiveness shall be verified through quality management system audits. Documented procedures for the identification and compliance of statutory and regulatory requirements concerning the quality and functionality of products and services as well as the legal disposal of waste shall be established and maintained. Employees affected shall be made aware of the importance of meeting these statutory and regulatory requirements.

The Quality Management System Organization with responsibilities for those personnel who manage, perform, and verify work affecting quality, needing the organizational freedom and authority to perform those tasks is documented as follows:



**President** - Overall in charge of the organization, keeping up the highest quality for the company.

**VP Manufacturing** - In charge of planning and the day to day activities of production, shipping and receiving. Ensures that the quality system is implemented in the production, shipping and receiving departments is followed by all personnel under his direction. Initiates corrective actions related to product, processes or quality system.

**Quality Manager** - Responsible for entire quality system and ensuring its compliance to ISO 9001:2000. Also responsible for the daily activities of the Quality Department and its personnel and their following of the policies and procedures. Initiates corrective actions related to product, processes or quality system.

**Sales Manager/Estimator** - Responsible for establishing relationships with customers and receive feedback on the effectiveness of the quality system and initiates corrective actions for customer complaints.

**All others** - Responsible for following all policies and procedures and understanding the quality management policy and notifying their supervisors when quality system requires attention.

**Quality Management (Subcontracted)** – As appropriate, may be responsible for quality related functions as follows: document reviews and approvals, initiation/recommendations involving corrective and/or preventive action (CAPA) for product, process or customer complaints, assistance in the maintenance of the QMS.

**Responsibilities:**

	Initiate Corrective Action			Identify and Record Problems			Initiate, recommend and provide solutions through designated channels	Verify implemented Solutions	Control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected
	Product	Process	Quality System	Product	Process	Quality System			
President	X	X	X	X	X	X	X	X	X
CEO	X	X	X	X	X	X			
Vice President	X	X	X	X	X	X	X	X	X
Quality Manager	X	X	X	X	X	X	X	X	X
Sales Manager/Estimator	X		X	X		X	X	X	X
Accounting									
Material Purchasing Manager	X		X	X		X	X	X	X
Shipping Receiving	X	X	X	X	X	X			X
Production Supervisors									
Operators	X	X	X	X	X	X	X	X	X

**5.2 Customer Focus (Quality Planning 4.2-1, Contract Review 4.3-2)**

With focus on customer satisfaction, the management of Arrow shall ensure that customer requirements are identified, defined and met. To monitor the effectiveness of these activities, customer satisfaction shall be part of management review.

**5.3 Quality Policy (Management Review 4.1-1)**

The management of Arrow shall issue and implement a company **Quality Policy** that meets the needs of Arrow and its customers. The quality policy shall include Arrow’s commitment for meeting internal requirements and customer requirements as well as the commitment for continual improvement, and shall provide a basis for the establishment and review of quality objectives. The quality policy shall be communicated within the organization and shall be understood and implemented by employees with responsibilities related to the achievement of the quality objectives. During management reviews, the quality policy shall be reviewed for its continuing suitability.

## 5.4 Planning (*Management Review 4.1-1, Quality Planning 4.2-1*)

### 5.4.1 Quality Objectives

Yearly quality objectives shall be established by MRC or its members for relevant areas of the company and approved by management. These quality objectives shall be measurable and consistent with the quality policy and shall, as appropriate, include that the requirements for products and/or service are met. Arrow Quality Policy and Quality Objectives are communicated as:

### *Quality Policy*

*The Management of Arrow Manufacturing Company is committed to quality and continual improvement in all areas of the company. Working as a team, management shall ensure that the company's objectives for quality and customer satisfaction is met.*

*Arrow's goal for quality is to maintain and to improve products and processes, in order to consistently meet customer needs as well as internal requirements.*

*Customer satisfaction is the company's main priority: we want to be our customers' preferred supplier.*

### *Quality Objectives*

- 1. To continually supply product which meets our customer's requirements.*
- 2. To reduce occurrences of nonconformance in our production process.*
- 3. To provide delivery on time according to our customers needs.*
- 4. To maintain customer satisfaction at its highest level.*

*Ed Selnau, President*

*June 25, 2003*

### 5.4.2 Quality Management System Planning

The Management Representative and MRC are responsible for the planning of the quality management system. Planning shall include the requirements specified in clause 4.1 as well as the achievement of quality objectives.

Organizational change resulting from planning activities shall be defined during the planning process and shall be performed in a controlled manner. As required, documents of the quality management system shall be updated.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority (*Management Review 4.1-1, Quality Planning 4.2-1*)

The overall responsibility for quality rests with the management of Arrow, consisting of the President and General Manager. The Management Representative is responsible for the control and administration of the quality management system. Management shall define the responsibility, authority and interrelation of functions within Arrow (QMS 5.2). Detailed individual responsibilities shall be defined in applicable operating procedures.

### 5.5.2 Management Representative (*Management Review 4.1-1*)

Arrow's management shall appoint the Management Representative for the quality management system. Irrespective of other responsibilities, the Management Representative shall have the responsibility and authority for the implementation and administration of the quality management system, its compliance with defined requirements and the achievement of customer satisfaction. The Management Representative shall report to management the performance and need for improvement of the quality management system, and shall ensure throughout the organization the awareness of meeting customer requirements.

### 5.5.3 Internal Communication (*Management Review 4.1-1*)

It is the responsibility of the Management Representative to ensure the effective communication between departments and functions concerned on quality related matters, and the effectiveness of the quality management system.

## 5.6 Management Review (*Management Review 4.1-1*)

Following the established documented quality management system procedure *Management Review 1.1*, at least once per year Arrow's management shall review and assess the quality management system regarding its suitability, adequacy, effectiveness and opportunities for improvement. Evaluation of the need for change of the quality management system, including the quality policy and objectives shall be part of the review process. Review activities shall also include the review of current performance and improvement opportunities resulting from: audits, customer feedback, process performance and product conformance analysis, status of preventive and corrective actions, follow-up actions from previous management reviews and changing circumstances. The results of management reviews shall be actions related to the improvement of the quality management system and its processes, of products and/or service related to customer requirements as well as the establishment of required resources.

Management reviews shall be documented and records shall be maintained as per established procedure.

## 6 Resource Management

### 6.1 Provisions of Resources (*Management Review 4.1-1, Quality Planning 4.2-1, Quoting 4.3-1, Process Control 4.9-1, Training 4.18-1*)

The requirements for resources are determined during quality planning. Management shall ensure that the human and material resources needed for the implementation and maintenance of processes of the quality management system are identified and available in a timely manner. This includes resources for improvements of the quality management system as well as resources required to meet customer requirements and ensure customer satisfaction.

### 6.2 Human Resources

#### 6.2.1 General (*Quality Planning 4.2-1*)

The Management Review Committee (MRC) shall ensure that personnel occupying functions defined in the quality management system shall be qualified and competent and shall have the required education, experience, skills and training for the assigned position.

## 6.2.2 Competence, Awareness and Training (*Training 4.18-1*)

It is the responsibility of the MRC to establish and maintain a documented procedure for training activities, qualification requirements and job awareness. The procedure shall include the awareness of employees regarding the impact of their roles and responsibilities on the quality of product and service, and on the achievement of quality objectives. The MRC or its members are responsible for identifying training needs and to ensure that required training is provided to personnel, in particular to personnel who perform activities affecting quality.

Job qualification requirements as well as job competence and training requirements shall be defined in individual job descriptions and shall be reviewed by the MRC or responsible department head.

The training effectiveness shall be evaluated during performance reviews conducted between supervisor and employee. Records of training, performance reviews, education and qualification shall be kept and maintained in the personal file of each employee.

## 6.3 Infrastructure (*Quality Planning 4.2-1, Process Control 4.9-1*)

It is the responsibility of the MRC or its members to identify, define, provide and maintain appropriate work facilities that are required for the performance of activities, processes and service in order to ensure conformance to specified requirements. Facilities shall include adequate workspace and associated utilities, equipment, hardware and software, suitable maintenance and other necessary supporting services.

## 6.4 Work Environment (*Process Control 4.9-1, Equipment Maintenance 4.9-2*)

It is the responsibility of the MRC and the department heads to ensure that a proper work environment for the achievement of quality and effectiveness is defined and present. The work environment shall meet internal and applicable regulatory requirements regarding health and safety, work methods and ambient working conditions.

## 7 Product Realization

### 7.1 Planning of Product Realization (*Quality Planning 4.2-1*)

Processes for product development and for the manufacture of products and service activities, including changes of these processes and activities, shall be defined during quality planning under the responsibility of the Engineering Department. All planning activities related to manufacturing and or service shall be conducted in close cooperation with Manufacturing or Technical Service, as applicable. The planning for product realization shall be consistent with clause 4.1 of this standard, and shall include as applicable: quality objectives and requirements for the product, as well as manufacturing plans which shall include necessary resources, documents, inspection and acceptance criteria, and records.

As required, the MRC or its members and/or department heads are responsible for the development of additional documents and procedures, and their implementation.

## **7.2 Customer-related Processes (*Quoting 4.3-1, Contract Review 4.3-2*)**

### **7.2.1 Determination of Requirements Related to the Product**

Customer requirements for product, service, packaging and delivery, applicable functional and performance requirements, as well as standards, statutory and legal requirements of the product or service, shall be determined by the responsible department. As appropriate, these identified requirements shall be used as input for quality planning.

### **7.2.2 Review of Requirements Related to the Product**

It is the responsibility of the Customer Service, MRC or its members to ensure that all required procedures for contract review and related activities are developed, documented, implemented and maintained.

Prior to the submission of a quotation or the acceptance of a contract or order, the quotation, contract or order shall be reviewed to ensure that all requirements are adequately determined and documented, that any differences between quotation and contract or order are resolved and that any missing or ambiguous specifications or statements are clarified and documented. Verbal requirements shall be confirmed prior to formal acceptance of the order or contract. Where required, and prior to submission of a quotation or the acceptance of a contract/order, appropriate reviews and studies are conducted to ensure that Arrow has the capability to meet the customer's requirements. Results of reviews and follow-up actions shall be recorded.

In case that amendments or changes to existing orders/contracts are required, Arrow's capability in meeting these new requirements shall be verified and confirmed by the quality planning team or functions concerned. As required, documents are updated and personnel affected shall be informed of the change. Records of contract reviews, follow-up actions and related activities are maintained as per established procedure.

### **7.2.3 Customer Communication**

Responsibilities for communication with customers regarding product and service information, general inquiries, ordering and order status, changes to existing orders, customer complaints, nonconforming products and customer feedback shall be defined and included in applicable operating procedures.

## **7.3 Design and Development (*Not applicable*)**

See section 3.1.1 Application Exclusion under General section 3, Scope 3.1.

## **7.4 Purchasing (*Purchasing 4.6-1, Subcontract Purchase 4.6-2, Supplier Control 4.6-3, Receiving Inspection 4.10-1*)**

### **7.4.1 Purchasing Process**

It is the responsibility of the Purchasing Department to establish procedures to ensure that purchased products conform to specified requirements, including statutory and regulatory requirements. The methods and type of control used for verification of purchased product shall depend on the effect of the purchased product on the final product and applicable production processes and service activities.

Suppliers shall be evaluated and selected according to defined selection criteria and their ability to supply product that meets specified requirements. The selection results and related actions shall be documented.

### **7.4.2 Purchasing Information**

It is the MRC's responsibility to set-up the purchased-product and supplier database files in the computer system. This data ensures that purchase orders do clearly describe the product, material or service ordered, including as applicable: approval or qualification requirements, quality management system requirements or other special requirements such as certificates of analysis or compliance, inspection reports as well as packaging, marking, labeling and shipping instructions. As appropriate, purchasing documents and/or purchasing data shall be reviewed and approved prior to release.

#### 7.4.3 Verification of Purchased Product

Purchased product shall be inspected and approved or rejected according to documented procedures established by Quality Assurance. If there is a need for Arrow or its customers to verify purchased products at the supplier's premises, these verification arrangements and applicable methods of product release shall be part of the purchasing contract and shall be according to requirements defined by MRC and/or Quality Assurance and/or Manufacturing.

### **7.5 Productions and Service Provision (*Customer Supplied Material 4.7-1, Product ID & Traceability 4.8-1, Process Control 4.9-1, Calibration 4.11-1, Inspection Status 4.12-1, Material Handling 4.15-1*)**

#### 7.5.1 Control of Production

During the Quality Planning Process under the responsibility of the QA Department, manufacturing processes shall be identified and planned and documented in Quality Plans, Service Plans and other suitable documents. Based on the output from quality planning, Manufacturing shall establish, maintain and implement procedures and operating instructions which describe in sufficient detail the product or service characteristics, and define the necessary equipment, monitoring devices and monitoring methods to be used in order to ensure that processes are carried out under controlled conditions. Included shall be procedures for release, delivery and post-delivery activities.

It is the responsibility of the MRC and VPMM to ensure that the working environment is appropriate for the work being performed and that it complies with applicable government regulations.

To ensure continuing process capability, Manufacturing shall implement and maintain a suitable maintenance program that includes applicable manufacturing equipment and provides for the timely replacement of parts.

#### 7.5.2 Validation of Processes for Production

As required, it is the responsibility of the Manufacturing and/or QA department to validate the capability of special processes. Special processes are production or service processes for which the output results cannot be verified through inspection or testing. These validations shall confirm that specified results are met. The control of special processes shall include acceptance criteria, necessary equipment and qualified personnel, operating instructions and required records. Revalidation shall be performed as required.

#### 7.5.3 Identification and Traceability

As appropriate, procedures shall be established and maintained by Manufacturing and/or Quality Assurance for the identification of product at receiving, during all stages of production, storage, delivery, installation and servicing. As applicable, this identification shall define the product, the actual acceptance or rejection status at all stages within the process, as well as the required data for traceability. Traceability records shall be maintained as per applicable master list of records.

#### 7.5.4 Customer Property

It is the responsibility of MRC to develop, implement and maintain documented procedures for identification, verification, storage and protection of property supplied/owned by the customer. Property may include M&ME, constituent materials or intellectual items such as drawings or specifications.

Any loss, damage, irregularities or nonconformity of customer owned property shall be recorded and reported to the customer. Records of these reports shall be maintained.

#### 7.5.5 Preservation of Product

It is the responsibility of the MRC and Manufacturing department to establish and maintain procedures for the identification, handling, storage, packaging for shipping, preservation and delivery of products. This includes the handling of parts and materials during production processes.

### 7.6 Control of Monitoring and Measuring Devices (*Calibration 4.11-1*)

The output from quality planning shall identify the measurements to be made and the measuring, testing and monitoring devices needed to assure conformance of product and service to specified requirements. As required, the suitability of computer software for measuring and monitoring activities shall be confirmed prior to use.

Quality Assurance shall establish and maintain procedures for the identification, control and storage, and periodic calibration and maintenance of measuring, monitoring and testing devices that is used to demonstrate conformance of product and service. Measuring and monitoring devices and software shall be kept in appropriate storage facilities and shall be used by qualified personnel to prevent improper use and damage. Calibration shall be performed according to a recognized standard; where no such standard is used, the method of calibration shall be documented. Calibration results shall be recorded and records shall be maintained according to the applicable master list of records.

In the event that measuring and monitoring devices are found out of calibration, previous verification results shall be validated and corrective action shall be taken as required, following the applicable established procedure. Records shall be maintained.

## 8 Measurement, Analysis and Improvement

### 8.1 General (*Management Review 4.1-1, Quality Planning 4.2-1*)

It is the responsibility of the Management Representative, the MRC, and QA Department to plan and implement appropriate monitoring and measuring activities in order to demonstrate the conformity of product to specified requirements, the conformity of the quality management system to planned objectives and results, and the achievement of continual improvement of the quality management system. Appropriate methodologies such as statistical techniques shall be determined and applied.

### 8.2 Monitoring and Measurement

## 8.2.1 Customer Satisfaction (*Management Review 4.1-1, Customer Satisfaction 4.20-4*)

At least once every twelve months, management shall conduct a customer satisfaction survey in order to obtain input and feedback directly from the customer regarding Arrow's achievement of customer satisfaction. This action is supported by statistics issued periodically about customer complaints and customer returns. The MRC, the President and other functions as appropriate analyze this data. Corrective and preventive actions are taken as required.

## 8.2.2 Internal Audit (*Internal Audits 4.17-1*)

It is the responsibility of the MRC or its members to establish maintain and implement documented procedures for planning and conducting internal quality audits. The procedure shall define the auditing process, responsibilities, reporting, necessary actions and records. Internal audits shall verify whether the quality management system meets ISO 9001 requirements and the internal requirements of Arrow, and whether it is effectively implemented and maintained. Internal audits shall verify if the outputs and objectives of quality planning specified in clause 7.1 are met.

Internal quality audits shall be planned and scheduled. All requirements of the ISO 9001 quality management system shall be audited at least once per year. The Management Representative shall ensure that qualified personnel, independent of those having direct responsibility of the area or activity to be audited, conduct internal quality audits. Auditors shall not audit their own work.

Required corrective action shall be taken, following established procedures. Where applicable, follow-up audits shall be conducted to verify the effectiveness of implemented corrective action. These actions shall be recorded. Internal audit results shall be reported to management and shall be part of management review.

## 8.2.3 Monitoring and Measurement of Processes (*Statistical Techniques 4.20-1, Pareto 4.20-2, SPC 4.20-3*)

As applicable, it is the responsibility of the Management Representative and department heads to use appropriate methods for the monitoring and verification of the processes of the quality management system. Monitoring and verification results shall confirm the ability of the quality management system in meeting quality objectives and defined requirements. If results do not meet requirements, corrective action shall be taken as appropriate.

## 8.2.4 Monitoring & Measurement of Product (*InProcess Inspection 4.10-2, Final 4.10-3, First Piece 4.10-4*)

It is the responsibility of Quality Assurance to establish and implement procedures for the monitoring and inspection of product to ensure that products received, products in production and during production, and products to be shipped, meet specified requirements. Verification activities are in accordance with the Manufacturing Plan. Records of verification results shall be maintained. These records shall identify the person who authorized the product release.

No product shall be shipped to customers until all acceptance criteria have been met, until final approval for shipping is given by Quality Assurance, or until other necessary approvals for the delivery are available.

## 8.3 Control of Nonconformity (*Nonconforming Product 4.13-1*)

It is the responsibility of Quality Assurance to establish and maintain documented procedures to ensure that nonconforming product received from suppliers, or in production or in inventory, is identified as nonconforming and is not available for production, sale, service or any other unintended use.

As per final disposition, the nonconforming product shall be released by authorized personnel for rework, acceptance with or without rework or with concession by the customer or applicable regulatory body, to be used for alternative application or to be rejected or scrapped. Reworked or repaired product is re-inspected by Quality Assurance according to the applicable Inspection Report.

In the event that nonconforming product is detected after the product was shipped to the customer or after its use in production or service, the QA Department and MRC shall analyze the impact of the nonconformity and shall take appropriate action.

#### **8.4 Analysis of Data (*Pareto Analysis 4.20-2*)**

As per established documented procedures, statistics on the performance of operational activities and customer satisfaction shall be issued by the Management Representative and shall be analyzed by MRC. Based on these analysis results, trends of product and service quality, the effectiveness and efficiency of operational activities as well as meeting customer requirements and customer satisfaction shall be established. The analysis shall include opportunities for improvement. Timely corrective and preventive actions shall be taken as required.

It is the responsibility of MRC or Purchasing to analyze supplier performance and take necessary action.

#### **8.5 Improvement (*Management Review 4.1-1, Pareto 4.20-2, Corrective& Preventive Action 4.14-1*)**

##### **8.5.1 Continual Improvement**

Continual improvement is the responsibility of all department heads. It is the responsibility of the Management Representative to coordinate activities for the continual improvement of the quality management system. Continual improvement shall be based on the quality policy, quality objectives, audit results, analysis of performance statistics, results of corrective and preventive actions and management reviews.

##### **8.5.2 Corrective Action**

The purpose of corrective action shall be the prevention of recurrence of nonconformities. The corrective action taken shall be appropriate to the importance of the problem or nonconformity.

The Management Representative shall establish documented procedures for a corporate approach for corrective action. The corrective action process shall address the identification of nonconformities and their review, including customer complaints. Nonconformities shall be analyzed, root causes shall be determined and necessary action shall be taken to prevent recurrence of the nonconformity. Corrective actions shall be recorded and results shall be monitored and reviewed regarding their implementation and effectiveness. Records of corrective actions shall be maintained.

##### **8.5.3 Preventive action**

Potential problems or nonconformities shall be identified and preventive action shall be taken to prevent their occurrence. Preventive action shall be appropriate to the probability of occurrence and the importance and impact of the potential problems or nonconformities. It is the responsibility of the Management Representative to establish documented procedures for a corporate approach for preventive action. The procedure(s) shall define the process for the identification of potential problems or nonconformities, the analysis of their impact and probability of occurrence, the need for preventive action, the implementation of actions, and the recording and monitoring of results of these preventive actions.

## Documentation Cross Reference Matrix

ISO 9001:2000	Policies	Procedures
<b>4.2 Documentation</b> 4.2.1 General 4.2.2 Quality manual 4.2.3 Control of documents 4.2.4 Control of records	4 Quality management system	4.2-1 Quality Planning 4.5-1 Quality Manual Control 4.5-2 Production Document Control, 4.5-3 External Document Control, 4.16-1 Quality Records
<b>5.1 Management commitment</b> <b>5.2 Customer focus</b> <b>5.3 Quality policy</b> <b>5.4 Planning</b> <b>5.5 Responsibility, authority and communication</b> <b>5.6 Management review</b>	5 Management responsibility	4.3-2 Contract Review 4.2-1 Quality Planning 4.1-1 Management Review
<b>6.1 Provision of resources</b> <b>6.2 Human resources</b> <b>6.3 Infrastructure</b> <b>6.4 Work environment</b>	6 Resource management	4.1-1 Management Review 4.2-1 Quality Planning 4.18-1 Training 4.9-1 Process Control
<b>7.1 Planning product realization</b> <b>7.2. Customer related processes</b>  <b>7.4 Purchasing process</b>  <b>7.5 Production provision</b> 7.5.1 Control of production 7.5.2 Validation of processes For production 7.5.3 Identification and traceability 7.5.4 Customer property 7.5.5 Preservation of Product  <b>7.6 Control of Monitoring and measuring Devices</b>	7 Product realization	4.2-1 Quality Planning 4.3-1 Quoting 4.3-2 Contract Review  4.6-3 Supplier Control 4.6-2 Subcontractor Purchasing 4.6-1 Purchasing Procedure 4.10-1 Receiving Inspection  4.9-1 Process Control 4.8-1 Lot Traceability 4.12.-1 Inspection & Test Status 4.7-1 Customer Supplied Product 4.15-1 Material Handling  4.11-1 Calibration
<b>8.1 General</b> <b>8.2. Monitoring and measurement</b> 8.2.1 Customer satisfaction 8.2.2 Internal audit 8.2.3 Monitoring and Measurement of Process 8.2.4 Monitoring and Measurement of Product  <b>8.3 Control of Nonconforming Product</b> <b>8.4 Analysis of data</b>  <b>8.5 Improvement</b> 8.5.1 Continual improvement 8.5.2 Corrective action 8.5.3 Preventive action	8 Measurement, analysis and improvement	4.20-3 Customer Satisfaction 4.17-1 Internal Audits 4.20-1 X-r SPC 4.20-2 Process Capability 4.10-3 In-Process Inspection 4.10-4 Final Inspection 4.10-2 First Piece Inspection  4.13-1 Nonconforming Product 4.20-4 Statistical Techniques, Pareto  4.1-1 Management Review 4.20-4 Statistical Techniques, Pareto 4.14-1 Corrective and Preventive Action

