

# A-M SYSTEMS

## QUALITY MANUAL

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**TITLE:** Quality Manager

**DATE:** 22-Sept-2011


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**APPROVED BY:** Arthur B. Green III

**TITLE:** President


**DATE:** 22-Sept-2011

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### Revision History

Rev.	Date	Changes
1	6/30/2006	Initial release.
2	8/16/06	Changes from BSI report # 4843532: 7.5: renumbering, missing sections, exclusions, scope, document outline, risk management.  First Internal audit comments.
3	9/22/06	Changes from BSI pre-assessment
4	11/3/06	Changes from BSI initial-assessment = NCR's 100168,100169
5	2/9/07	Added reference to Policies and Procedures QSP6.2.3
6	4/19/07	Added QSP-7.2 Customer Related Processes to appropriate areas in 7.5
7	5/8/07	Specifically indicated the FDA and Canadian MDR where Regulatory bodies were mentioned
8	9/6/07	Update the quality policy per management review 8/22/07
9	12/4/07	Update the Signature page to reflect new Quality Manger Name.
10	2/24/08	DCR #200484. Update QM to more closely resemble numbering of ISO standard. Added EU MDD references where Regulatory bodies mentioned.
11	3/18/08	DCR #200521. Add CMDR and MDD to Quality Policy statement as per BSI audit recommendation. Added sections 6.2.3 and 6.5.
12	5/05/08	DCR #200546. Clarify wording in section 7.2.3.
13	12/01/08	DCR #200656. Modify Quality Policy to reflect new company president.
14	06/02/09	DCR #200793 adds "QSP 7.3.2" to QM-1 4.1.2 Quality System Process Interaction.
15	09/09/10	DCR #201325. Add new service-related objective to Quality Policy.
16	09/22/11	DCR #201619. Update organization chart to add CFO.


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## COMPANY PROFILE

A-M SYSTEMS (A-M Systems) is located in Sequim, Washington two hours west of Seattle. Our Pulmonary division offers respiratory supplies to hospitals, clinics and doctors. Our Physiology division offers electronic equipment: electrodes, capillary glass and accessories to universities, government and industry bio-medical research labs.

A-M Systems has been committed to providing our customers with the highest quality products promptly and economically since 1976. Most of our products are kept in stock at all times for same day shipping. The real key to A-M Systems' success lies with an absolute commitment to quality from every employee. From top-level management down, in all phases of design, manufacture and customer service, everyone must be genuinely dedicated to providing the best product possible.

A-M Systems now produces a wide variety of products, shipping to customers all over the country and across the world. Although the product line and customer base has grown, A-M Systems' philosophy remains the same: Produce the best product possible for both the patient and the operator and build in the best quality in the industry. A-M Systems' high standards are maintained by always striving for continuous improvement of engineering and manufacturing techniques. This allows us to keep our costs down and helps us to maintain very competitive pricing.

A-M Systems has developed and implemented the Quality Management System outlined in this Quality Manual to ensure that its products, standards, and services meet or exceed the rigorous requirements demanded by our customers. The Quality Management System is considered by the management of A-M Systems to be an integral and essential part of all company operations.

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## QUALITY POLICY


A-M Systems' strategic mission is to earn customer business by providing high quality products at a great value and to provide prompt delivery. A-M Systems intends to fulfill this mission by achieving the highest marks on A-M Systems' key objectives:

- To provide competitively priced quality products.
- To promote a friendly work environment.
- To achieve high customer satisfaction.
- To engage in business transactions with high quality suppliers.
- To continually grow both domestically and internationally.
- To offer a service program to help ensure continued compliance and performance of A-M Systems products in post-production.

A-M Systems has developed this quality management system to comply with ISO 13485:2003, FDA Quality System Regulations (21 CFR PART 820), EU Medical Device Directive (MDD 93/42/EEC), Canada Medical Device Regulations (SOR/98-282), and any other relevant regional regulatory requirements. A-M Systems will focus management review efforts on continual improvement of our quality system.

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Arthur B. Green III, President

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## 1. Scope

### 1.1. General

The Quality Manual identifies the scope of the Quality Management System maintained by A-M Systems. The purpose is to provide the controls necessary to:

- Achieve the highest possible quality standards for all products and services provided by A-M Systems.
- Determine the needs and expectations of customers and other interested parties
- Recognize and implement all customer and statutory requirements
- Motivate and control the human resources that affect process quality for the purpose of identifying, reducing, and ultimately preventing all quality deficiencies
- Establish the quality policy and objectives of A-M Systems
- Determine the processes and responsibilities necessary to attain the quality objectives
- Determine and provide the resources necessary to attain the quality objectives
- Establish methods to measure the effectiveness and efficiency of each process.


### 1.2. Application

#### 1.2.1. General

A-M Systems designs, manufactures, and distributes non-invasive medical devices for pulmonary/respiratory therapy, and instruments and accessories for neuroscience research.

#### 1.2.2. Exclusions

No exclusions are taken to the requirements listed in the ISO 13485:2003 at this time.

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### 1.2.3. Non-applicability


The following sections of the ISO 13485:2003 standard are non-applicable for A-M Systems:

- **6.4c, 6.4d** Work environment. A-M Systems does not have special environmental conditions, or deal with potentially contaminated product.
- **7.5.1.2.1** Cleanliness of product and contamination control.
  - The majority of A-M Systems products do not require cleaning prior to use. For these products 7.5.1.2.1 does not apply. However A-M Systems does have some reusable products. All products that require sterilization include instructions for use that indicate this as per the requirement of 7.5.1.2.1. For these products the following do not apply under 7.5.1.2.1:
    - **From 7.5.1.2.1 6.4a, and 6.4b** do not apply to A-M Systems products that are intended to be cleaned and sterilized
    - **7.5.1.2.1a** A-M Systems does not clean any products prior to use or sterilization.
    - **7.5.1.2.1d** A-M Systems does not remove process agents.
- **7.5.1.2.2** Installation activities, A-M Systems does not install devices
- **7.5.1.3, 7.5.2.2** sterile medical devices, A-M System does not manufacture sterile devices
- **7.5.3.2.2, 8.2.4.2** implantable medical devices, A-M Systems does not manufacture active implantable medical devices or implantable medical devices

## 2. Reference Documents

- ISO 13485:20003(E) – Quality Management System Requirements
- A-M SYSTEMS - Quality System Procedures, Forms and Work Instructions
- 21 CFR, Part 820 – Quality System Regulations
- 21 CFR, Part 801 – Labeling Instructions
- A-M Systems FDA Policies and Procedures Manual
- Canada Medical Device Regulations (SOR/98-282)
- EU Medical Device Directive (MDD 93/42/EEC)
- ISO 14971 - Medical devices — Application of risk management to medical devices
- ISO 14969 Guidance for ISO 13485
- ANSI/ASQC M1-1996: American National Standard for Calibration Systems
- ANSIASQ Z1.4-2003: American National Standard sampling procedures and tables for inspection by attributes



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### 3. Definitions

Medical Device: Medical Device: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  - investigation, replacement, modification, or support of the anatomy/physiological process,
  - supporting or sustaining life,
  - control of conception,
  - disinfection of medical devices,
  - providing information for medical purposes by means of in vitro examination of specimens derived from the human body,
- and which does not achieve its primary intended action in or on the human body by pharmacological, Immunological or metabolic means, but which may be assisted in its function by such means.

Manufacturer: natural or legal person with responsibility for the design, manufacture, packaging or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Quality: is a degree to which a set of inherent characteristics fulfills requirements. The term quality is also defined as a totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Product: is a result of an interrelated or interacting activity or process.

Top Management: is a person or group of people who direct and control an organization at the highest level. (See A-M SYSTEMS' Organization Chart QF-5.5\_1)

Continual Improvement: is a recurring activity to increase the ability to fulfill requirements. The process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective action or preventive action.

Design history file (DHF): a compilation of records which describes the design history of a finished device or family of devices.

Device history record (DHR): a compilation of records containing the production history of a finished device or family of devices.

Device master record (DMR): a compilation of records containing the procedures and specifications for a finished device or family of devices.

Labeling: written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Lot: one or more components, finished devices, or products that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality.


Part Specifications (PS): a document that lists items necessary to make, purchase, and inspect a part.

Product Documentation (PD): a document that lists everything necessary to make, inspect, and ship a product.

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#### 4. Quality Management System

##### 4.1. General Processes

In order to better meet the requirements of regulatory bodies including:

- FDA Quality System Regulations as set forth in 21 CFR PART 820,
- Labeling instructions outlined in 21 CFR Part 810,
- Canadian Medical Device Regulations (SOR/98-282),
- EU Medical Device Directive (MDD 93/42/EEC),
- And other applicable regulatory bodies,

A-M Systems has established documented, implemented and maintains a quality management system in accordance with the requirements of the ISO 13485:2003 Standard.

A-M Systems has:

- Identified the processes needed for the quality management system and their application throughout the organization
- Determined the sequence and interaction of these processes
- Determined criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensured the availability of resources and information necessary to support the operation and monitoring of these processes; is monitoring, measuring and analyzing the data from these processes and implementing any actions necessary to achieve planned results and continual improvement.

Where A-M Systems chooses to outsource any process that may affect product conformity with requirements, they ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system, and overseen by the Quality Manager.


**Supporting Procedure:** <Q:\QSP\QSP-8.1 Regulatory Bodies.pdf>

##### 4.1.1 Quality Management System Planning

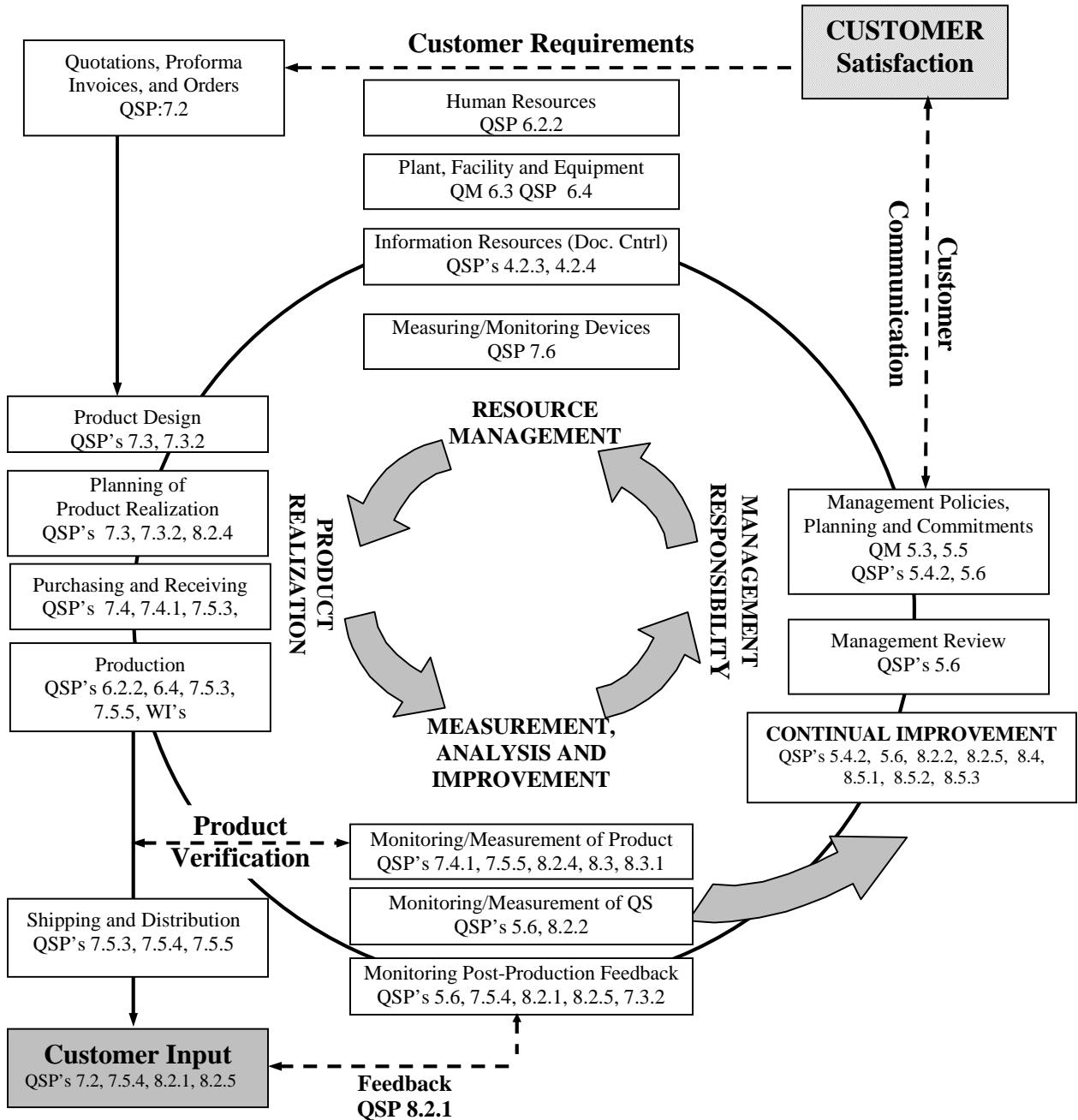
An important element of managing the A-M Systems organization is the implementation and maintenance of an effective quality management system that is designed to enable the organization to provide medical devices that meet customer and regulatory requirements.


A-M Systems can maintain the effectiveness of its established quality management system through a range of activities, including, but not limited to:

- Internal audits
- Management review
- Corrective and preventive actions
- Independent external assessments

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#### 4.1.2 Quality System process interaction



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## 4.2. Documentation and Records

### 4.2.1. General

The quality management system consists of documented statements of the quality policy, quality objectives, the quality manual, documented procedures required by the ISO 13485:2003 Standard, documents for planning, operation and process control, industry regulatory requirements and all required records referenced in this manual. A file containing or identifying documents that define product specification and quality management system requirements is maintained for each type or model of medical device.

**Supporting Procedure:** <Q:\QSP\QSP-8.1 Regulatory Bodies.pdf>

### 4.2.2 Quality System Document Structure

Level 1: Outlines the quality plan – This document, the Quality Manual: QM-1

Level 2: Defines who, what, and when - All Quality System Procedures: QSP's'

Level 3: Answers how to tasks – Instructions:


- External documents (DOC)
- Mechanical Drawings (DRG, DRW. IGS)
- General documents (GEN)
- Electrical Drawings (GRB, DRG)
- Assembly work instructions (WI)
- General work Instructions (WI)

Level 4: Records:

- Design History Files (DHF)
- Device Master Record (DMR)
- Product Definitions (PD)
- Part Specification (PS)
- Quality Forms (QF)
- Work Forms (WF)
- Technical Files (TF)

### 4.2.3 Quality Manual

This quality manual defines the scope of the quality management system, including details of and justification for any exclusion. The Quality Manual references the procedures detailing the actual means by which the system operates and demonstrates the interaction between the processes which make up the system. Changes to the Quality manual that effect conformity to ISO 13485 or Regulatory requirements are submitted to the Registrar used by A-M Systems.

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#### 4.2.4 Control of Documents

Documents required by the quality management system are controlled. Records are a special type of document and are controlled according to the requirements given in 4.2.4, Control of Records.

A procedure has been established that defines the controls needed to:

- Review and approve documents for adequacy prior to issue.
- Review and update as necessary and re-approve documents.
- 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 are identified and their distribution controlled.
- Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
- Identify the period for which controlled documentation is retained as defined in the appropriate regulations
- Maintain obsolete documents

Changes to documentation are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information on which to base decisions. Changes to documentation that effect conformity to ISO 13485 or regulatory requirements are submitted to the appropriate body.

**Supporting Procedure:** <Q:\QSP\QSP-4.2.3 Control of Documents.pdf>

#### 4.2.5 Control of Records


Records are prepared and retained according to regulatory requirements and to provide evidence of the effective operation of the quality management system. Records remain legible, readily identifiable and readily retrievable. A documented procedure has been established that defines the controls needed for the identification, storage, protection, retrieval, retention times and disposition of records.

**Supporting Procedure:** <Q:\QSP\QSP-4.2.4 Control of Records.pdf>

### 5. Management Responsibility

#### 5.1. Management Commitment

The General Manager and/or Quality Manager has provided documented evidence of his commitment to the development and implementation of the quality management system and continually improving and maintaining its effectiveness by:

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- Communicating to A-M Systems through the quality management system the importance of meeting customer as well as statutory and regulatory requirements.
- Establishing the quality policy.
- Continually ensuring that quality objectives are established and met.
- Conducting periodic management reviews.
- Maintaining regulatory requirements (licensing, new design, design changes, NCR, recall, etc.).
- Ensuring the availability of necessary resources.

**Supporting Procedure:** [Q:\QSP\QSP-5.6 Management Review.pdf](#)


## **5.2. Customer Focus**

The General Manager ensures customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction. This is done through any one or more of the following:

- Determining the requirements specified by the customer, including the requirements for delivery.
- Determining the requirements not stated by the customer but necessary for specified use or known and intended use through past history, experience and/or customer needs.
- Determining the statutory and regulatory requirements related to the product.
- Monitoring information relating to customer perception as to whether A-M Systems has fulfilled customer requirements, through customer satisfaction trend analysis, rejections, performance, on-time delivery, etc.
- Focusing on process improvement, ensuring value.

**Supporting Procedure:** [Q:\QSP\QSP-7.2 Customer Related Processes.pdf](#)

**Supporting Forms:** [Q:\QF\QF-8.2 4 Customer Service Survey.doc](#)

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### 5.3. Quality Policy

Top management has ensured that the quality policy:

- Is appropriate to its purpose
- Includes a commitment to comply with all requirements, both of the Standard and applicable regulations, and to continually improve the effectiveness of the system
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood within the organization
- Is periodically reviewed for continuing suitability.
- The company's quality policy is documented and signed in section 1.

### 5.4. Planning

#### 5.4.1. Quality Objectives


The General Manager ensures quality objectives, including those needed to meet requirements for the product (product manager), are established for relevant functions (Senior Engineer) and levels within the organization (General Manager). The quality objectives shall be measurable and consistent with the quality policy and include the planning of product realization (Production Manager) to include the quality objectives (Quality Manager) and requirements for the product (Product Manager).

When objectives are being established, management may evaluate any or all of the following:

- Current and future needs of A-M Systems and industry
- Relevant findings from management review meetings
- Product and process performance
- Levels of satisfaction, internal and external
- Assessment results
- Competitor analysis, bench marking, new opportunities for improvement, and
- Continually sourcing new resources needed to fulfill quality objectives.

Objectives are systematically reviewed and revised, as necessary.

Supporting Procedure: <Q:\QSP\QSP-5.6 Management Review.pdf>

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#### 5.4.2. Quality Management System Planning

The General Manager ensures the planning of the quality management system is carried out in order to meet the requirements given in the quality manual section 4.1, as well as the quality objectives, and that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

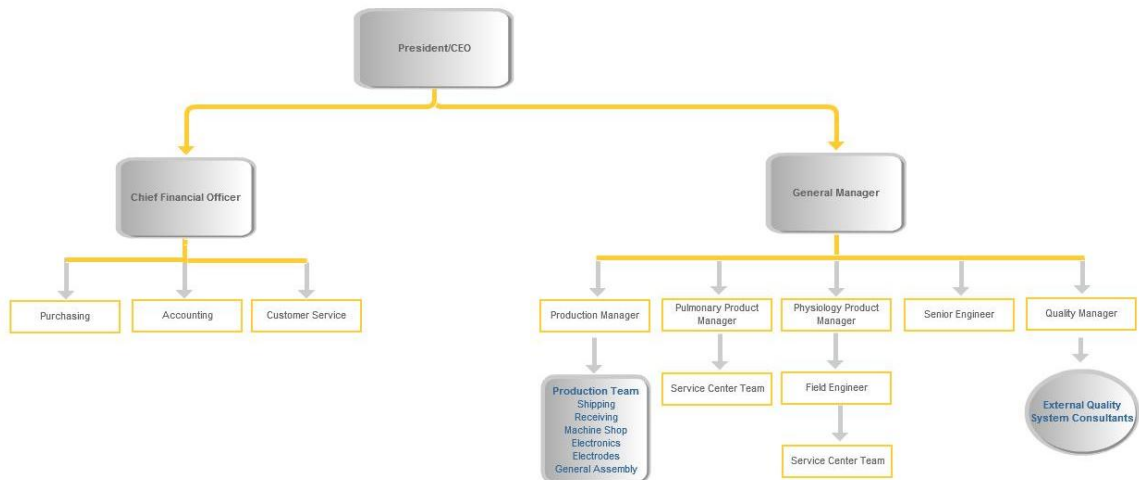
**Supporting Procedure:** [Q:\QSP\QSP-5.4.2 Quality Management System Planning.pdf](#)

#### 5.5. Responsibility, Authority and Communication

##### 5.5.1. Responsibility and Authority

The General Manager has ensured responsibilities and authorities are defined, documented and communicated within the organization. The General Manager has established the interrelation of all personnel involved in any facet of quality, or whose work affects quality, ensuring these employees have the independence and authority necessary to perform their tasks. These relationships are outlined below and assigned in the Organization Chart.


**Supporting Form:** [Q:\QF\QF-5.5\\_1 Organizational Chart.doc](#)



##### 5.5.2. Management Representative

The General Manager has appointed a Quality Representative, who irrespective of other responsibilities has responsibility and authority for:



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- Ensuring that processes needed for the quality management system are established, implemented and maintained.
- Reporting to top management on the performance, effectiveness and any deficiencies in the quality management system and any need for improvement.
- Ensuring promotion of the awareness of regulatory and customer requirements throughout the organization.

### 5.5.3. Internal Communication

The General Manager ensures appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

## 5.6. Management Review

### 5.6.1. General

The General Manager reviews the organization's quality management system, at least twice a year, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and policy objectives.

### 5.6.2. Review Input

The input to management review includes information on:

- Results of audits
- Customer feedback.
- Process performance and product conformity.
- Status of preventive and corrective actions.
- Follow-up actions from previous management reviews.
- Any changes that could affect the quality management system.
- Recommendations for improvement.
- New or revised regulatory requirements.


### 5.6.3. Review Output

The output from the management review states any decisions and actions related to:

- Improvements needed to maintain the effectiveness of the quality management system and its processes.
- Improvement of product related to customer requirements.
- Planning objectives and action requirements.
- Resource needs.

Records of management review are maintained following 4.2.4, Control of Records.

**Supporting Procedure: [Q:\QSP\QSP-5.6 Management Review.pdf](#)**

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## 6. Resource Management

### 6.1. Provision of Resources

General Manager has determined and provided the resources needed to implement and maintain the quality management system, continually improve its effectiveness, and to enhance customer satisfaction by meeting customer and regulatory requirements.

### 6.2. Human Resources

#### 6.2.1. General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

#### 6.2.2. Competence, Awareness, and Training

Top management has:

- Determined the necessary competence for personnel performing work affecting product quality
- Provide training or taken other actions to satisfy these needs
- Evaluated the effectiveness of the actions taken.
- Ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- Maintained appropriate records of education, training, skills and experience following 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-6.2.2 Competence, Awareness and Training.pdf>

**Supporting Procedure:** <Q:\QSP\QSP-6.2.3 Policies and Procedures.pdf>

#### 6.2.3. Policies and Procedures

A major goal of A-M Systems is to keep our employees informed of current policies and updated information. Therefore, we have published a comprehensive statement of Policies and Procedures and Explanation of Employee Benefits to help meet this objective. We feel that this handbook, when understood and referenced by employees, is one way we can accomplish this goal.

**Supporting Procedure:** <Q:\QSP\QSP-6.2.3 Policies and Procedures.pdf>


### 6.3. Infrastructure

A-M Systems has determined, provides and maintains the infrastructure needed to achieve conformity to product requirements. The Infrastructure includes:

- Buildings, workspace and associated utilities;
- Process equipment, both hardware and software
- Supporting services such as transport or communication.

Associated maintenance activities are performed and documented following QSP, 4.2.4, Control of Records.

**Supporting Form:** <Q:\QF\QF-7.5 3 Maintenance Schedule.doc>

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#### 6.4. Work Environment

A-M Systems has determined and manages the work environment needed to achieve conformity to product requirements. The requirements for the work environment take into account the following:

- Processes set up in that location;
- Level of skill required
- Quality of environment; heat, humidity, light, and air
- Safety factors associated with process or equipment
- Level of supervision
- Possible requirements for the training and supervision of temporary employees if necessary

**Supporting Procedure:** <Q:\QSP\QSP-6.4 Environmental Control.pdf>

#### 6.5. Employee Safety Program

A-M Systems places a high value on the safety of its employees. Top management is committed to providing a safe workplace for all employees and has developed a program for injury prevention to involve management, supervisors, and employees in identifying and eliminating hazards that may develop during our work process. The goal of the program is zero injuries.

**Supporting Procedure:** <Q:\QSP\QSP-6.5 Accident Prevention Program.pdf>

### 7. Product Realization

#### 7.1. Planning of Product Realization

The General Manager plans and develops the processes needed for product realization. Planning or product realization is consistent with the requirement of the other processes of the quality management system.

When planning product realization, management determines the following as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes, documents, and provide resources specific to the product.
- Required verification, validation, monitoring, inspection and test activities specific to the product, and the criteria for product acceptance.
- Records needed to provide evidence that the realization processes and resulting product meet regulatory, registration, and realization requirements.
- The application of risk management techniques as appropriate.

The output of this planning is in a documented form suitable for A-M Systems' method of operation. Records are retained following QSP-4.2.4, Control of Records.


**Supporting Procedure:** <Q:\QSP\QSP-7.3.2 Risk Management.pdf>

#### 7.2. Customer Related Processes

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

Management determines:

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- Requirements specified by the customer, can be met.
- Requirements not stated by the customer but necessary for specified use or known and intended use of the final product.
- Statutory and regulatory requirements related to the product can be met.
- Any additional requirements deemed necessary by the organization based on experience, knowledge and history of the product.

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

All proposals and contracts are reviewed prior to the organization's commitment to supply a product to the customer and shall ensure that:

- Product requirements are defined, accepted and documented, including special requirements.
- Contract or order requirements differing from those previously expressed are resolved and accepted.
- The organization has the ability to meet the defined requirements.

Where the customer provides no documented statement of requirements, the customer requirements are confirmed before accepting the order.

Any contract change, order amendment, specification change or delivery variations to an existing order or contract, are to be subjected to the contract review above. Once the change has been formally approved, the revised information is immediately communicated to the responsible individuals.

Records of the results of the review and actions arising from the review shall be maintained per paragraph 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-7.2 Customer Related Processes.pdf>

### 7.2.3. Customer Communication

Management has selected and implemented a method for effectively communicating with customers concerning:

- Product information
- Enquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints and advisory notices.
- Customer communication is done by authorized personnel.

Critical quality or service related communications with customers are documented and become part of the quality records.

**Supporting Forms:** [Q:\QF\QF-8.2\\_4 Customer Service Survey.doc](Q:\QF\QF-8.2_4 Customer Service Survey.doc)

## 7.3. Design and Development


### 7.3.1. Design and Development Planning

The acquisition of new process equipment and/or the development of new products, processes, delivery methods and/or any significant change in the company's operations are critical opportunities for effective quality control review. The impact of changing production dynamics on quality control must be carefully assessed and become an integral and proactive part of the planning process. Procedure QSP-7.3, Design and Development has been established that outlines design from the early stage to final product.

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The Product Managers identify and document the planning goal(s) as well as plan and control the design and development of product. Plans describe or reference these activities, and define responsibility for design implementation. Planning output is updated, as appropriate, or as the design and development progress. Qualified personnel or their designee with adequate resources, coordinate developmental activities for each new design project. The Product Managers determines:

- The design and development stages
- The review, verification and validation, and design transfer activities that are appropriate to each design and development stage
- The responsibilities and authorities for design and development

The Product Managers are responsible for identifying and coordinating the necessary interface between all parties involved in, or potentially affected by the design, including customer and regulatory authorities.

The Product Managers manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

Design procedures are to be developed to provide the flow of all-pertinent design information and changes for the purpose of regular review and/or comment.

### **7.3.2. Design and Development Inputs**


The functional and performance requirements of any new design, product, or process shall be developed through analysis of past quality problems; product failures; contract review documentation; statutory requirement; and customer or company standards. These findings are to be documented or referenced in the design plan.

Inputs relating to product requirements are determined and records maintained per paragraph 4.2.4, Control of Records. These shall include:

- Functional performance and safety requirements, according to the intended use;
- Applicable statutory and regulatory requirements;
- Information derived from previous similar designs, where applicable;
- Other requirements essential for design and development; and
- Outputs of risk management.

The Product Managers shall review these inputs for adequacy and approval. Requirements shall be complete, unambiguous and not in conflict with each other.

**Supporting Procedure: [Q:\QSP\QSP-7.3.2 Risk Management.pdf](#)**

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### 7.3.3. Design and Development Outputs

The purpose of the Design Plan is to clearly identify design output requirements prior to the commencement of any new design task. The outputs of design and development shall be provided in a form that enables verification against the design and development input and are approved prior to release. Records are maintained following QSP-4.2.4, Control of Records.

Design and development outputs:

- Meet or exceed the input requirements for design and development;
- Provide appropriate information for purchasing, production and for service provision;
- Contain or clearly reference product acceptance criteria; and
- Specify the characteristics of the product that are essential for its safe and proper use.

### 7.3.4. Design and Development Review

The progress of design work is reviewed in formal review meetings attended by representatives of the department(s) ultimately responsible for the commissioning and operation of the design. At suitable intervals, systematic reviews of design and development shall be conducted:

- To evaluate the ability of the results of design and development to fulfill requirements; and
- To identify problems and propose necessary actions.


Participants in such reviews shall include representatives of the functions concerned with the design and development stages(s) being reviewed, as well as other specialist personnel, suppliers or customers. Records of the results of the reviews and any necessary actions shall be maintained per paragraph 4.2.4, Control of Records.

### 7.3.5. Design and Development Verification

Design verification is essential. Verification shall be performed to ensure that the design and development outputs have satisfied the design and development input requirements. The specific duties of the design verification team may include:

- Performing alternative calculations
- Comparing the new design with alternative designs and/or options
- Arranging product and process tests
- Reviewing design work-in-progress documents before release.

Records of the results of the verification and any necessary actions shall be maintained per paragraph 4.2.4, Control of Records.

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#### **7.3.6. Design and Development Validation**

Design and development validation shall be performed in accordance with planned arrangements following the design and development planning, stated in paragraph 7.3.1, Design and Development Planning, after successful design verification or as soon as practical. The purpose of design and development validation is to ensure that the resulting product is capable of fulfilling the requirements for the specified intended use or application.

Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. National or regional regulatory clinical evaluations and/or evaluation of performance are conducted on the medical devices, if required. The results of such tests are to be thoroughly documented for comparison against later results. If there are different intended uses, multiple validations may be required.

Records of the results of validation and any necessary actions shall be maintained per paragraph 4.2.4, Control of Records.

#### **7.3.7. Control of Design and Development Changes**

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved by the Product Managers prior to implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and delivered product.

Records of the results of the review of changes and any necessary actions shall be maintained per paragraph 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-7.3 Design and Development.pdf>

#### **7.4. Purchasing**

##### **7.4.1. Purchasing Process**

A process has been established to ensure that purchased items or services conform to the specified purchase requirements. The type and extent of control applied to the supplier or subcontractor and the purchased item or service is dependent upon the effect of the purchased item or service on subsequent product realization or the final product.


A-M Systems evaluates and selects suppliers and subcontractors based on their ability to supply items or services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation have been established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained per paragraph 4.2.4, Control of Records.

##### **7.4.2. Purchasing Information**

Purchasing information defines the item or service to be purchased, including where appropriate:

- Requirements for approval of product, procedures, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements
- Traceability requirements. Copies of relevant purchasing documents are retained, where necessary, for purposes of traceability as defined in paragraph 7.5.3

Purchase orders are reviewed and approved prior to transmission.

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### 7.4.3. Verification of Purchased Product

A-M Systems performs inspection or other activities to the extent necessary to ensure that purchased items or services meet the specified purchase requirements.

Where A-M Systems or its customers intend to perform verification at the supplier's premises, A-M Systems shall define the intended verification arrangements and method of product release in the purchasing information. Records of verification are maintained following QSP-4.2.4.

**Supporting Procedure:** <Q:\QSP\QSP-7.4 Purchasing.pdf>

**Supporting Procedure:** <Q:\QSP\QSP-7.4.1 Supplier Evaluation.pdf>

## 7.5. Production Provision

### 7.5.1. Control of Production Provision

#### 7.5.1.1 General requirements

A-M Systems plans and carries out production under controlled conditions. Controlled conditions include, as applicable:

- The availability of documented information that describes the characteristics of the product.
- The availability of any necessary documented work instructions, reference materials and reference standards.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of suitable monitoring and measurement.
- The implementation of release and delivery activities.
- The implementation of defined operations for labeling and packaging.
- Lot records are maintained for each medical device to comply with requirements for traceability. These records show the quantity manufactured and the quantity released to the customer and are verified and approved.

#### 7.5.1.2 Control of production and service Provision – specific requirements

##### 7.5.1.2.1. Cleanliness of Product and Contamination Control

Documented procedures describe, as applicable, the method and extent of cleaning each product undergoes prior to its shipment to the customer. Individual work instructions provide more detailed cleaning beyond those specified in QSP-6.4 if it is of significant to its use.


**Supporting Procedures:** [Individual Work Instructions](#)

**Supporting Procedure:** <Q:\QSP\QSP-6.4 Environmental Control.pdf>

##### 7.5.1.2.2. Installation activities

A-M Systems does not provide installation activities



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#### 7.5.1.2.3. Servicing activities

Documented procedures or work instructions describe, as applicable the method and extend for performing servicing activities. Service records are maintained through service reports (QF-7.5\_4), or customized reports.

**Supporting Procedures: Individual Work Instructions**

#### 7.5.1.3 Particular requirements for sterile medical devices

A-M Systems does not provide sterile devices

### 7.5.2. Validation of processes for production and service provision

#### 7.5.2.1 General requirements

A-M Systems validates any process where subsequent monitoring or measurement cannot verify the resulting output. This includes any process where deficiencies become apparent only after the product is in use.

Validation demonstrates the ability of these processes to achieve planned results


A-M Systems establishes arrangements for such processes, including, as applicable:

- Defined criteria for review and approval of the processes.
- Equipment and personnel.
- Use of specific methods and procedures.
- Full compliance with all relevant regulatory standards and codes.
- Maintenance of production equipment.
- Plans for any necessary recalibrations
- Requirements for records, paragraph 4.2.4, Control of Records.

Special processes are monitored in accordance with the above criteria, but with special attention to ensure that all process specifications and other exceptional monitoring and compliance requirements are fully met.

Documentation exists for the validation of computer software for production or monitoring purposes, where such application can affect the ability of the product to conform to specified requirements. Applications are validated prior to initial use. Records are maintained following QSP-4.2.4, Control of Records.

**Supporting Procedures: Individual Work Instructions**

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### 7.5.3. Identification and Traceability

Supporting Procedure: <Q:\QSP\QSP-7.2 Customer Related Processes.pdf>

Supporting Procedure: <Q:\QSP\QSP-7.5.3 Identification and Traceability.pdf>

#### 7.5.3.1 Identification

As appropriate, in-process product, finished product, returned product and nonconforming product and materials are identified by suitable means.

#### 7.5.3.2 Traceability

Where applicable, the extent and thoroughness of the method of traceability is agreed upon between the customer and A-M Systems, with documented details approved by both parties, before work commences. Maintained records include the name and address of the shipping package consignee. Records shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market

#### 7.5.3.3 Status identification

Product status, with respect to monitoring and measurement requirements, is maintained throughout production ensuring that only conforming product is released, unless authorized by concession, to the customer.

#### 7.5.4. Customer Property

A-M Systems exercises care with customer property, including intellectual property, while it is under the control or being used by A-M Systems. Customer property is identified, verified, protected and safeguarded when provided for use or incorporation into the product.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be immediately reported to the customer.

Records shall be maintained per paragraph 4.2.4, Control of Records.

Supporting Procedure: <Q:\QSP\QSP-7.5.4 Customer Property.pdf>

Supporting Procedure: <Q:\QSP\QSP-7.2 Customer Related Processes.pdf>


#### 7.5.5. Preservation of Product

A-M Systems preserves the conformity of product during internal processing and delivery to the intended destination according to documented procedures. These procedures address limited shelf life, identification, handling, packaging, storage and protection as applicable. Preservation shall also apply to the constituent parts of a product. The exact criteria for handling, storing, packaging, preserving and delivery of each product are defined in the relevant process documentation.

Special conditions are recorded as required and follow QSP-4.2.4, Control of Records.

Supporting Procedure: <Q:\QSP\QSP-7.5.5 Preservation of Product.pdf>

Supporting Procedure: <Q:\QSP\QSP-7.2 Customer Related Processes.pdf>

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#### 7.6. Control of Monitoring and Measuring Devices

A-M Systems determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed, to provide evidence of conformity of product to determined requirements following paragraph 7.2.1, Determination of Requirements Related to the Product.

A-M Systems has established a documented procedure to ensure that monitoring and measurement is carried out in a manner that is consistent with the monitoring and measurement requirements.


Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification 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

In addition the validity of previous measurement results is assessed and recorded when the equipment is found not to conform to requirements. Appropriate action is then taken on the equipment and any product affected. Records of the results of calibration and verification shall be maintained per paragraph 4.2.4, Control of Records.

Computer software, when used in the monitoring and measurement of specified requirements, will be assessed for its ability to satisfy the intended application. This shall be undertaken prior to initial use and reconfirmed as necessary.

Supporting Procedure: [Q:\QSP\QSP-7.6 Control of Monitoring and Measuring Devices.pdf](#)

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## 8. Measurement, Analysis, and Improvement

### 8.1. General

A-M Systems plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- demonstrate conformity of the product
- ensure conformity of the quality management system
- maintain the effectiveness of the quality management system
- continually improve the effectiveness of the quality management system

This includes determination of applicable methods, including statistical techniques, especially where the use of such techniques is a regulatory requirement.

Records are maintained per paragraph 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-5.6 Management Review.pdf>

**Supporting Procedure:** <Q:\QSP\QSP-8.2.2 Internal Quality Audits.pdf>

### 8.2. Monitoring and Measurement

#### 8.2.1. Feedback

Customer supplied information is continually monitored to see if their requirements are being met. A documented feedback system provides early warning of quality problems and input for possible corrective or preventive action.

**Supporting Procedure:** <Q:\QSP\QSP-8.2.1 Customer Feedback and Post Market Surveillance.pdf>

**Supporting Forms:** [Q:\QF\QF-8.2\\_4 Customer Service Survey.pdf](Q:\QF\QF-8.2_4 Customer Service Survey.pdf)

#### 8.2.2. Internal Audit

A-M Systems conducts internal audits at planned intervals to determine whether the quality management system conforms to:

- Appropriate regulatory requirements including 21 CFR part 820 and 801
- The planned arrangements following paragraph 7.1, Planning of Product Realization
- The requirements of the ISO 13485:2003(E) International Standard
- The quality management system requirements established by the organization and,
- Is effectively implemented and maintained.

Internal audits are necessary to verify the implementation and measure the effectiveness of A-M Systems' total quality performance. Top management is responsible for the selection and training of the Auditor(s). Auditors shall not audit their own areas of responsibility.


Each element of the quality system is audited regularly; a minimum of once per year, in accordance with documented procedures. Depending on the criticality of the activity/area to be audited and the results of previous audits this frequency may be increased. The audit criteria, scope, frequency and methods are defined.

The results of each audit are documented and distributed to top management, and those persons responsible for the activities/areas that have been audited. When an audit report

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identifies significant quality failures and/or recommends immediate remedial action, the person responsible for the audited activity/area is to plan and initiate corrective action in a timely manner.

Follow-up audits, include the verification of the actions taken and the reporting of verification results follow paragraph 8.5.2, Corrective Action, and serve to confirm that all necessary corrective actions have been taken.

The person responsible for the area/activity that has been audited shall ensure that actions are taken, without undue delay, to eliminate detected nonconformities and their causes.

The responsibilities and requirements for reporting results and maintaining records follow paragraph 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-8.2.2 Internal Quality Audits.pdf>

### **8.2.3. Monitoring and Measurement of Processes**

The organization 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. Correction and preventative action shall be taken as appropriate, when planned results are not achieved, to ensure conformity of the product.

Records of such activities are documented and maintained per paragraph 4.2.4, Control of Records.

**Supporting Procedure:** <Q:\QSP\QSP-8.5.2 Corrective Action.pdf>

### **8.2.4. Monitoring and Measurement of Product**


#### **8.2.4.1 General requirements**

A-M Systems monitors and measures the characteristics of the product to verify that requirements are fulfilled and have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements following section 7.1, Planning of Product Realization and documented procedures or instructions outlined in section 7.5.

Inspection and Test Records:

- Product release and service delivery shall not proceed until all the planned arrangements following section 7.1, Planning of Product Realization have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.
- Evidence of conformity with the acceptance criteria shall be maintained.
- Records shall indicate the person(s) performing any inspection or testing and those authorizing release of the product.

**Supporting Procedure:** <Q:\QSP\QSP-8.2.4 Monitoring and Measurement of Product.pdf>

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### 8.3. Control of Nonconforming Product

A-M Systems ensures that product and materials or components, which do not conform to product requirements, are identified and controlled to prevent their unintended use or delivery to a customer. The responsibility and controls for identifying nonconforming items, and the authority to order their disposition, are contained in QSP-8.3, Control of Nonconforming Product. Where nonconforming product is sourced from a subcontractor, then its disposition and/or rework, and any further corrective action shall be mutually agreed between A-M Systems' authorized representative and the subcontractor.

#### 8.3.1.1 Nonconformity Review and Disposition

Nonconforming product may be identified at any stage of the process and, when identified, is held, recorded, re-inspected and dispositioned of in an approved manner. The disposition method may be one of the following:

- By taking action to eliminate the detected nonconformity.
- By authorizing its use, release or acceptance under concession by the customer only when regulatory requirements can be met (CMDR, FDA, MDD, etc.).
- By taking action to preclude its original intended use or application.
- Notification of regulatory bodies where applicable (CMDR, FDA, MDD, etc.).

Reworked product is documented and the rework method is documented and approved prior to commencement. Part of the authorization and approval of the rework process includes the determination of any adverse effects the rework may cause. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the Company takes action appropriate to the effects or potential effects of the nonconformity.

Records are maintained of all inspection and testing of nonconforming product and materials and all subsequent re-inspection or retesting.

**Supporting Procedure:** <Q:\QSP\QSP-8.3 Control of Nonconforming Product.pdf>

### 8.4. Analysis of Data


A-M Systems identifies, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system, and to evaluate where improvement of the quality management system can be made.

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
- supplier performance and suitability

**Supporting Procedure:** <Q:\QSP\QSP-8.4 Analysis of Data.pdf>

**Supporting Forms:** <Q:\QF\QF-8.2 4 Customer Service Survey.doc>

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## 8.5. Improvement

### 8.5.1. General

A-M Systems identifies and implements any changes necessary to ensure and maintain the continued suitability and 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.

A procedure has been established for assisting our customers with necessary information should they need to issue an Advisory Notice.

Customer complaints are recorded and, as necessary, subjected to corrective and preventive action processes, and if this is determined not to be required, the justification and authorization shall be recorded and maintained.

**Supporting Form:** <Q:\QSP\QSP-8.5.1 Continual Improvement.pdf>

### 8.5.2. Corrective Action

A-M Systems takes action, when necessary, to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

The Quality System Procedure, QSP-8.5.2, describes the method for corrective action as follows:


- Review of nonconformities including customer complaints.
- Determination of the causes of nonconformities.
- Evaluation of the need for action to ensure that nonconformities do not recur.
- Selection and implementation of appropriate steps to eliminate the cause(s) of nonconformities.
- Record results of investigations and actions taken.
- Review and monitor the effectiveness of any corrective action(s) that are taken.

Records with results of action taken are maintained per paragraph 4.2.4, Control of Records.

**Supporting Form:** <Q:\QSP\QSP-8.2.5 Customer Complaints.pdf>

**Supporting Form:** <Q:\QSP\ QSP-8.3.1 Advisory Notices, Recalls, and Vigilance.pdf>

**Supporting Procedure:** <Q:\QSP\QSP-8.5.2 Corrective Action.pdf>

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### 8.5.3. Preventive Action

A-M Systems takes action, as appropriate, to eliminate the causes of potential nonconformities in order to prevent their future occurrence. Preventive actions are appropriate to the probable effects of the potential nonconformities.

The Quality System Procedure, QSP-8.5.3, describes the method for preventive action as follows:

- Determine the potential for a nonconformity and its possible cause
- Evaluate the need for action
- Plan and implement specific preventive actions as determined necessary.
- Record the results of any investigations and actions taken.
- Monitor and review any preventive action taken and its effectiveness.

Records of the preventive action are maintained per paragraph 4.2.4, Control Of Records

Supporting Form: <Q:\QSP\QSP-8.2.5 Customer Complaints.pdf>

Supporting Form: <Q:\QSP\ QSP-8.3.1 Advisory Notices, Recalls, and Vigilance.pdf>

Supporting Procedure: <Q:\QSP\QSP-8.5.3 Preventive Action.pdf>