A-M SYSTEMS

QUALITY MANUAL

ORIGINATED BY: Robert J. Thompson

TITLE: Quality Manager

DATE: _____

_____

APPROVED BY: Arthur B. Green III

TITLE: President and CEO

DATE: _____

_____

Revision History

Rev.	Date	Changes
1	6/30/06	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 resemble numbering of ISO standard more closely. 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 objectives to the Quality Policy.
16	09/22/11	DCR #201619. Update organization chart to add CFO.
17	03/13/17	DCR #202677. Update section 1.2.3 to remove section 6 from non-applicability. Update quality policy page to remove the phrase "highest marks" as well as the word "any" from the last paragraph.
18	01/22/18	DCR #202908. Update QM for compliance with 2016 version of ISO 13485 standard.
19	04/05/19	DCR #203179. Update Quality Policy to include quality slogan. Add numbering and appropriate headers to sections 4.1.1 – 4.1.7.
20	05/01/19	DCR #203201. Identify 7.5.10 Customer Property as a permissible exclusion.
21	04/15/20	DCR #203326. Update Quality Policy to revise references from EU MDD to MDR.
22	05/15/20	DCR #201619. Update Quality Policy quality objective bullet points with criteria and goals.
23	04/21/2021	DCR #203501. Update section 4.4.1 to include roles undertaken by the organization as required in the ISO 13485:2016 standard. Also update MDD references throughout the quality manual to instead reference EU MDR.
24	09/28/2021	DCR #203609. Section 2 Reference Documents updated to include missing reference documents.

		DCR # 203610. Section 4.1.5 revised to include listing of outsourced processes and point to need for quality agreement which must define controls of these outsourced processes. DCR # 203611. Section 5.5.3 revised to include forms of approved internal communication.
25	10/31/2023	DCR #203969. Add section 7.5.10 Customer Property back to the appropriate location in the QM, as the company has acquired customer property since the original removal as per notes in revision 20. Remove 7.5.10 Customer Property from the non-applicable section of the QM (section 1.2.3).
26	01/06/2025	DCR # 204016. Updated reference for 4.1.6, 7.5.6 and updated 7.2 and 7.5.10 into other/additional areas of flowchart. Section 4.1.5 revised to include detailed listing of outsourced processes in table format.

1. Scope **8**
1.1. General **8**
1.2. Application **8**
1.2.1. General 8
1.2.2. Exclusions 8
1.2.3. Non-applicability 9
2. Reference Documents **9**
3. Definitions **9**
4. Quality Management System **11**
4.1.1. General QMS Requirements 11
4.1.2 Definition of Process Management 11
4.1.3. Process Effectiveness 12
4.1.4. Process Change 12
4.1.5. Outsourcing of Processes 12
4.1.6. Software Application Validation 14
4.1.7. Quality System process interaction 15
4.2. Documentation and Records **16**
4.2.1. General 16
4.2.2 Quality System Document Structure 16
4.2.3 Medical Device File 16
4.2.4 Control of Documents 17
4.2.5 Control of Records 18
5. Management Responsibility **18**
5.1. Management Commitment **18**
5.2. Customer Focus **18**
5.3. Quality Policy **19**
5.4. Planning **19**
5.4.1. Quality Objectives 19
5.4.2. Quality Management System Planning 20
5.5. Responsibility, Authority and Communication **20**
5.5.1. Responsibility and Authority 20
5.5.2. Management Representative 20
5.5.3. Internal Communication 21
5.6. Management Review **21**
5.6.1. General 21
5.6.2. Review Input 21
5.6.3. Review Output 21
6. Resource Management **22**
6.1. Provision of Resources **22**
6.2. Human Resources **22**
6.2.1. General 22
6.2.2. Competence, Awareness, and Training 22
6.2.3. Policies and Procedures 23
6.3. Infrastructure **23**
6.4. Work Environment and Contamination Control **24**
6.5. Employee Safety Program **24**
7. Product Realization **24**
7.1. Planning of Product Realization **24**
7.2. Customer Related Processes **25**
7.2.1. Determination of Requirements Related to the Product 25
7.2.2. Review of Requirements Related to the Product 25
7.2.3. Communication 25

7.3. Design and Development 26
7.3.1. General 26
7.3.2. Design and Development Planning 26
7.3.3. Design and Development Inputs 27
7.3.4. Design and Development Outputs 27
7.3.5. Design and Development Review 27
7.3.6. Design and Development Verification 28
7.3.7. Design and Development Validation 28
7.3.8. Design and Development Transfer 28
7.3.9. Control of Design and Development Changes 29
7.3.10. Design and Development Files 29
7.4. Purchasing 29
7.4.1. Purchasing Process 29
7.4.2. Purchasing Information 29
7.4.3. Verification of Purchased Product 30
7.5. Production and Service Provision 30
7.5.1. Control of Production and Service Provision 30
7.5.2. Cleanliness of Product and Contamination Control 31
7.5.3. Installation activities 31
7.5.4. Servicing activities 31
7.5.5. Particular Requirements for sterile medical devices 31
7.5.6. Validation of processes for production and service provision 31
7.5.7. Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems 32
7.5.8. Identification 32
Supporting Procedure: Q:\QSP\QSP-7.2 Customer Related Processes.pdf 32
7.5.9. Traceability 33
7.5.10. Customer Property 33
7.5.11 Preservation of Product 33
7.6. Control of Monitoring and Measuring Devices 34
8. Measurement, Analysis, and Improvement 34
8.1. General 34
8.2. Monitoring and Measurement 35
8.2.1. Feedback 35
8.2.2. Complaint Handling 35
8.2.3. Reporting to Regulatory Authorities 35
8.2.4. Internal Audit 36
8.2.5. Monitoring and Measurement of Processes 36
8.2.6. Monitoring and Measurement of Product 36
8.3. Control of Nonconforming Product 37
8.3.1. General 37
8.3.2. Actions in Response to Nonconforming Product Detected Before Delivery 37
8.3.3. Actions in Response to Nonconforming Product Detected After Delivery 37
8.3.4. Rework 38
8.4. Analysis of Data 38
8.5. Improvement 39
8.5.1. General 39
8.5.2. Corrective Action 39
8.5.3. Preventive Action 40

COMPANY PROFILE

A-M SYSTEMS (A-M Systems) is 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 always kept in stock 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.

QUALITY POLICY

"Our Family, Our Quality and Service, Your Solution"

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 focusing on A-M Systems' key objectives:

- To provide high quality products.
- To promote a safe work environment.
- To achieve high customer satisfaction.
- To engage in business transactions with high quality suppliers.

The above-stated goals and their effectiveness criteria will be documented and measured using QF-5.6_2 Quality Objectives & Goals Report or another type of spreadsheet and will be evaluated for their effectiveness at each management review meeting.

Product quality (a) will be measured by analyzing returned products returned due to quality issues as compared to total invoices and total products shipped. The goal is to have less than 1% of products shipped returned due to quality issues.

A safe work environment (b) will be measured by analyzing hours lost to work due to work-related injury as compared to total hours worked. An injury is work-related when an event or exposure in the work environment caused or contributed to the injury. The goal is to have less than 1% of hours lost to work related injury.

Customer satisfaction (c) will be measured by analyzing valid customer complaints as compared to total invoices and total products shipped. Complaints are valid when they involve a product quality issue, or another type of error deemed to be the fault of the organization. The goal is to have less than 1% of valid complaints compared to all invoices and less than 0.5% valid complaints compared to all products shipped.

Supplier quality (d) will be measured by analyzing vendor NCR's requiring corrective actions as compared to vendor purchase orders. The goal is to have less than 3% of purchase orders requiring a vendor NCR with corrective action when compared to total purchase orders for a given period.

A-M Systems has developed this quality management system to comply with ISO 13485:2016, FDA Quality System Regulations (21 CFR PART 820), MDR (EU) 2017/745, Canada Medical Device Regulations (SOR/98-282), and other applicable regulatory requirements. Top management shall remain committed to complying with requirements and maintaining the effectiveness of the quality management system by focusing management review efforts on the continual improvement of our quality system.

Arthur B. Green III, President

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 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 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 and respiratory therapy.

1.2.2. Exclusions

Physiology and neuroscience products and processes are to be excluded from the requirements listed in the ISO 13485:2016 standard. These products are not for human use and therefore should not be included in the scope of this quality manual.

1.2.3. Non-applicability

The following sections of the ISO 13485:2016 standard are non-applicable for A-M Systems:

- **7.5.2** Cleanliness of product and contamination control.
    - Most A-M Systems' products do not require cleaning prior to use. For these products 7.5.2 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 7.5.2. For these products, the following do not apply under 7.5.2:
        - **From 7.5.2, 6.4.1a and 6.4.1b** do not apply to A-M Systems products that are intended to be cleaned and sterilized.
        - **7.5.2a** A-M Systems does not clean any products prior to use or sterilization.
        - **7.5.2e** A-M Systems does not remove process agents.
- **7.5.3** Installation activities, A-M Systems does not install devices.
- **7.5.5, 7.5.7** sterile medical devices, A-M System does not manufacture sterile devices.
- **7.5.9.2**, **8.2.6(paragraph 4)** implantable medical devices, A-M Systems does not manufacture active implantable medical devices or implantable medical devices.

2. Reference Documents

- ISO 13485:2016– 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
- 21 CFR, Part 803 – Medical Device Reporting
- 21 CFR, Part 806 - Medical Devices; Reports of Corrections and Removals
- 21 CFR, Part 821 – Medical Device Tracking Requirements
- A-M Systems FDA Policies and Procedures Manual
- Canada Medical Device Regulations (SOR/98-282)
- EU Medical Device Regulations (MDR 2017/745)
- MDSAP Companion Document – Audit Approach
- ISO 14971 - Medical devices — Application of risk management to medical devices
- ANSI/ASQC M1-1996: American National Standard for Calibration Systems
- ANSIASQ Z1.4-2008: American National Standard sampling procedures and tables for inspection by attributes

3. Definitions

Medical Device: instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, 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 medical purposes 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 or of a physiological process.
- supporting or sustaining life.
- control of conception.
- disinfection of medical devices.
- providing information by means of *in vitro* examination of specimens derived from the human body.

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note 1 to entry: Products which may be medical devices in some jurisdictions but not in others include:

- disinfection substances.
- aids for people with disabilities.
- devices incorporating animal and/or human tissues.
- devices for *in vitro* fertilization or assisted reproduction technologies.

Manufacturer: natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).
Distributor: natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Importer: natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.
Lifecycle: all phases in the life cycle of a medical device, from initial conception to final decommissioning and disposal.
Medical device family: group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.
Post-market surveillance: systematic process to collect and analyze experience gained from medical devices that have been placed on the market.
Risk: combination of the probability of occurrence or harm and the severity of that harm.
Risk Management: the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.
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 bears on its ability to satisfy stated and implied needs.
Product: is a result of an interrelated or interacting activity or process.
Complaint: written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices.
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 using 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: Label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper 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.

4. Quality Management System

4.1.1. General QMS Requirements

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 801,
- Canadian Medical Device Regulations (SOR/98-282),
- EU Medical Device Regulations (MDR 2017/745),
- And other applicable regulatory bodies

The roles undertaken by A-M Systems, by jurisdiction, include:

FDA

- Manufacturer,
- Repackager/Relabeler

Health Canada

- Manufacturer,
- Distributor

EU

- Manufacturer (select Class 1 devices)

A-M Systems has established, documented, implemented, and maintains a quality management system in accordance with the requirements of the ISO 13485:2016 Standard.

4.1.2 Definition of Process Management

A-M Systems has:

- Identified the processes needed for the quality management system and their application throughout the organization considering the roles undertaken by the organization (as identified in section 4.1.1).
- Applied a risk-based approach to the control of appropriate processes needed for the quality management system.
- Determined the sequence and interaction of these processes. (Section 4.1.7)

4.1.3. Process Effectiveness

A-M Systems has:

- 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.
- Monitoring, measuring, and analyzing the data from these processes and implementing any actions necessary to achieve planned results and continual improvement.
- Established and maintained records needed to demonstrate conformance to this ISO 13485:2016 and with applicable regulatory requirements.

4.1.4. Process Change

A-M Systems has ensured that changes made to these processes shall be:

- evaluated for their impact on the quality management system.
- evaluated for their impact on the medical devices produced under this quality management system.
- controlled in accordance with the requirements of the ISO 13485:2016 standard and applicable regulatory requirements.

4.1.5. Outsourcing of Processes

Where A-M Systems chooses to outsource any process that may affect product conformity with requirements, they monitor and ensure control over such processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4 (Purchasing). The controls shall include written quality agreements which are to include:

- Clearly defined processes that are being outsourced
- Specified quality requirements
- Roles and responsibilities of A-M Systems and partner to whom processes are outsourced
- Requirement for certificates of conformance
- Required availability of lot/batch test data
- Established right to audit supplier

Control of such outsourced processes is identified in the table below and overseen by the Quality Manager.

Outsourced Process according to ISO 13485:2016	Outsourced Process in Confluence	Control Over the Outsourced Process
6.3 Infrastructure 6.4 Work Environment	Partially Outsourced: • QSP-6.3 Infrastructure • QSP-6.4 Work Environment and Contamination Control	A-M Systems manages its own infrastructure, including key equipment, information systems and the local backups. The offsite backup is partially outsourced to Olypen which hosts the offsite backup server. Olypen also provides the fiber internet connection to the facility. Olypen is controlled by the standard Supplier Evaluation procedure. A-M Systems manages its own work environment and but does outsource the Pest Control service to a vendor. This vendor is controlled by the standard Supplier Evaluation procedure: QSP-7.4.1 Supplier Evaluation QF-7.5_3 Maintenance Schedule QF-7.5_8 IS Maintenance Schedule Contract Manufacturers maintain their own work environment. A-M Systems maintains control of this via standard vendor review processes and periodic on-site audits: QF-7.4_6 Vendor Evaluation QF-8.2_22 Vendor Audit Schedule QF-8.2_21 Supplier Audit Plan
7.5 Production and Service Provision	Partially Outsourced: • QSP 7.1 Planning of Product Realization	A-M Systems employs a contract manufacturer for production and assembly of many Pulmonary parts and products. The contract manufacturer is considered a Critical Supplier which entails a more robust level of control by the organization. These controls include a Quality Agreement, the standard supplier evaluation process, and periodic on-site supplier audits: QF-7.4_8 Critical Supplier List QSP-7.4 Purchasing QSP-7.4.1 Supplier Evaluation QF-8.2_22 Vendor Audit Schedule QF-8.2_21 Supplier Audit Plan
7.6 Control of Monitoring and Measuring Devices	Partially Outsourced: • QSP-7.6 Control of Monitoring and Measuring Devices	A-M Systems manages many of the monitoring and measuring devices in-house and but does outsource certain calibration services to a vendor. This vendor is controlled by the standard Supplier Evaluation procedure: QF-7.4_6 Vendor Evaluation QF-7.6_3 Equipment List WI-1121 In house calibration of instruments and jigs

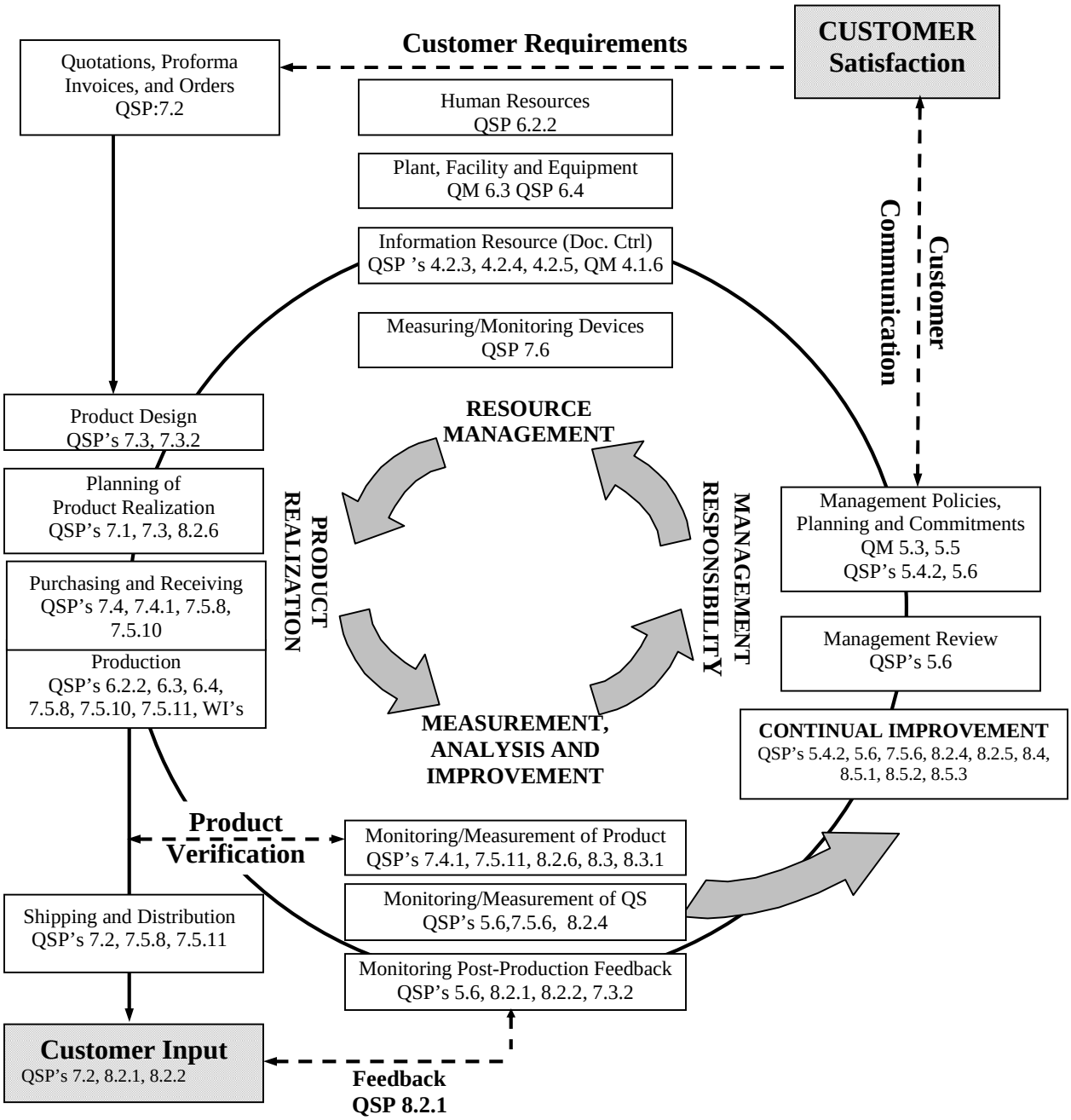
		Report – Equipment Calibration Due Report
Regulatory Compliance	Partly Outsourced: QSP-8.1 Regulatory Bodies	A-M Systems manages its own Regulatory Compliance and but does outsource certain elements. A vendor is contracted for EU and CH Authorized Representative services. This vendor maintains a contract for service and is controlled by the standard Supplier Evaluation procedure: QSP-7.4.1 Supplier Evaluation

4.1.6. Software Application Validation

A-M Systems shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and as appropriate, after changes to such software or its application.

Supporting Procedure: Q:\QSP\QSP-4.1.6 Software Application Validation

4.1.7. Quality System process interaction



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 13485:2016 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 Medical Device File

A file is maintained for each device, and device family, which contain documentation or evidence of conformity of the device to the ISO 13485:2016 standard and applicable regulatory requirements. The contents of the file shall include, but is not limited to:

- general description of the medical device.
- intended use/purpose.
- labelling, including any instructions for use.
- specifications for product.

- specifications or procedures for manufacturing, packaging, storage, handling, and distribution.
- procedures for measuring and monitoring.
- as appropriate, requirements for installation.
- as appropriate, procedures for servicing.

Supporting Procedure: Q:\QSP\QSP-4.2.3 Medical Device File.pdf

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 4.2.5, 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.
- Prevent deterioration or loss of 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 affect conformity to ISO 13485 or regulatory requirements are submitted to the appropriate body.

A-M Systems shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization but not less than the retention period of any resulting record or as specified by applicable regulatory requirements.

Supporting Procedure: Q:\QSP\QSP-4.2.4 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. Further, the organization has determined that no confidential health information is contained in our records and therefore no special methods need to be documented to ensure their protection.

Supporting Procedure: Q:\QSP\QSP-4.2.5 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:

- 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 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

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 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 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

5.4.2. Quality Management System Planning

The General Manager ensures the planning of the quality management system is carried out 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.

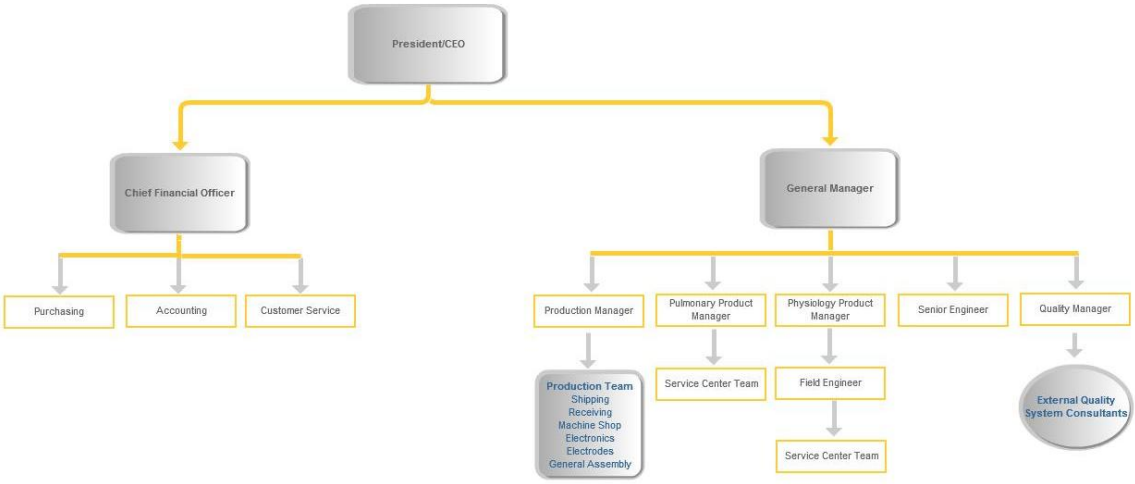
Supporting Procedure: Q:\QSP\QSP-5.4.2 Quality Management System Planning.pdf

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:

- 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.

Approved forms of internal communication include:

- Weekly status meetings
- Email
- Scrum meetings
- Microsoft Teams

The company employs an open-door policy whereby any employee is encouraged to engage and talk with management as needed.

5.6. Management Review

5.6.1. General

The General Manager reviews the organization's quality management system via management review meetings at documented planned intervals. A-M Systems meets at least twice a year, to ensure its continuing suitability, adequacy, and effectiveness. The rationale for this frequency will be documented during each management review meeting. 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:

- Customer feedback
- Complaint Handling
- Reporting to Regulatory Authorities
- Results of audits, internal, supplier and third party
- Monitoring and Measurement of Processes (Process performance and product conformity)
- Status of preventive and corrective action,
- Follow-up actions from previous management reviews, and review of planned changes that could affect the quality management system.
- Recommendations for improvement, and
- Applicable New or revised regulatory requirements.

5.6.3. Review Output

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

- Improvement needed to maintain the sustainability, adequacy, and effectiveness of the quality management system and its processes.
- Improvement of product related to customer requirements.
- Changes needed to respond to applicable new or revised regulatory requirements.
- Resource needs
- Documentation of the justification for the frequency of management reviews

Records of management review are maintained following 4.2.5, Control of Records.

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

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.

A-M Systems has a documented procedure for establishing competence, providing needed training, and ensuring awareness of personnel.

6.2.2. Competence, Awareness, and Training

Top management will:

- Determine the necessary competence for personnel performing work affecting product quality.
- Provide training or take other actions to satisfy these needs.
- Evaluate the effectiveness of the actions taken. The extent of the evaluation of training effectiveness may be proportionate to the risk associated with the work for which the training or other action is being provided.
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- Maintain appropriate records of education, training, skills, and experience following 4.2.5, 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

Supporting Form: Q:\QF\QF-6.2_10 Employee Training Effectiveness Review

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, prevent product mix-up and ensure orderly handling of product. The infrastructure includes, as appropriate:

- Buildings, workspace, and associated utilities.
- Process equipment, both hardware and software.
- Supporting services such as transport, communication, or information systems.
- Protection of sensitive and confidential company and customer information via access controls relating to physical and digital property.

Associated maintenance activities are performed and documented following QSP, 4.2.5, Control of Records.

Supporting Procedure: Q:\QSP\QSP-6.3 Infrastructure.pdf
Supporting Procedure: Q:\QSP\QSP-8.7 Information Security Policy.pdf

Supporting Form: Q:\QF\QF-7.5_3 Maintenance Schedule.doc

Supporting Form: Q:\QF\QF-7.5_8 Information Systems Maintenance Schedule.doc

6.4. Work Environment and Contamination Control

A-M Systems has determined and manages the work environment needed to achieve conformity to product requirements. The documented requirements for the work environment consider 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 Work Environment and Contamination 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, including infrastructure and work environment.
- Required verification, validation, monitoring, inspection and test, handling, storage, distribution, and traceability 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-4.2.5, 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:

- 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 user training needed to ensure specified performance and safe use of the medical device.
- 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.
- Applicable regulatory requirements are met.
- Any user training identified in accordance with 7.2.1 is available or planned to be available.
- The organization can 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. ‘

Where any changes to specifications or documents must be communicated with a supplier, the supplier must acknowledge and confirm the changes using the Document Change Receipt Acknowledgement form.

Records of the results of the review and actions arising from the review shall be maintained per paragraph 4.2.5, Control of Records.

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

7.2.3. 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.

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

7.3. Design and Development

7.3.1. General

The organization shall maintain a documented procedure for design and development.

7.3.2. 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.

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 methods to ensure traceability of design and development outputs to design and development inputs.
- The resources needed, including necessary competence of personnel.

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.

7.3.3. 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, usability, 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, able to be verified or validated, and not in conflict with each other.

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

7.3.4. 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-4.2.5, 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.

7.3.5. 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 4.2.5, Control of Records and include the identification of the design under review, the participants involved and the date of the review.

7.3.6. 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.

The organization shall document verification plans the include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet the design inputs when so connected or interfaced.

Records of the results of the verification and any necessary actions shall be maintained per paragraph 4.2.5, Control of Records.

7.3.7. 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 7.3.2, 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 can fulfill the requirements for the specified intended use or application.

The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.

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 4.2.5, Control of Records.

7.3.8. Design and Development Transfer

The organization shall maintain a documented procedure for transfer of design and development outputs to manufacturing. This procedure shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

Records of the design transfer shall be maintained per paragraph 4.2.5, Control of Records.

7.3.9. 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, delivered product, products in process, inputs or outputs of risk management and product realization processes.

Records of the results of the review of changes and any necessary actions shall be maintained per paragraph 4.2.5, Control of Records.

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

7.3.10. Design and Development Files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include, or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

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. Supplier evaluations will also be based on the effect of the purchased product on the quality of the device and proportionate to the risk associated with the device. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained per paragraph 4.2.5, 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
- A written agreement or acknowledgment that the supplier notifies the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.
- Traceability requirements: Copies of relevant purchasing documents are retained, where necessary, for purposes of traceability as defined in paragraph 7.5.9 and as per paragraph 4.2.5 Control of Records.

Purchase orders are reviewed and approved prior to transmission.

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.

The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When A-M Systems becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.

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-4.2.5.

Supporting Procedure: Q:\QSP\QSP-7.4 Purchasing.pdf

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

7.5. Production and Service Provision

7.5.1. Control of Production and Service Provision

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.

7.5.2. 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 Work Environment and Contamination Control.pdf

7.5.3. Installation activities

A-M Systems does not provide installation activities.

7.5.4. 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

7.5.5. Particular Requirements for sterile medical devices

A-M Systems does not provide sterile devices.

7.5.6. Validation of processes for production and service provision

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 4.2.5, 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-4.2.5, Control of Records.

Supporting Procedures: Individual Work Instructions

7.5.7. Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

A-M Systems does not provide or manufacture any sterile products.

7.5.8. Identification

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

Identification of product status shall be maintained throughout the production, storage, installation, and servicing of product to ensure that only product that has passed the required inspection and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, the organization will document a system to assign unique device identification to the medical device.

The company will also maintain a procedure to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

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

Supporting Procedure: Q:\QSP\QSP-7.5.8 Identification and Traceability.pdf

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

7.5.9. Traceability

As appropriate, in-process product, finished product, returned product and nonconforming product and materials are identified by suitable means and records are maintained per paragraph 4.2.5, Control of Records.

7.5.9.1 General

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.

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.

Supporting Procedure: **Q:\QSP\QSP-7.5.8 Identification and Traceability.pdf**

7.5.10. Customer Property

A-M Systems identifies and protects all customer property provided for use by a customer. This is to include measuring and test equipment, raw materials, products intended to be packaged with our own products, and any intellectual property under the control of A-M Systems. This would include confidential health information as well, but A-M Systems does not possess or maintain any confidential health data.

Supporting Procedure: **Q:\QSP\QSP-7.5.10 Customer Property.pdf**

7.5.11 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-4.2.5, Control of Records.

Supporting Procedure: **Q:\QSP\QSP-7.5.11 Preservation of Product.pdf**

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

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 4.2.5, 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

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 4.2.5, Control of Records.

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

Supporting Procedure: Q:\QSP\QSP-8.2.4 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.

A-M Systems maintains a documented procedure for the feedback process. The feedback process shall include provisions to gather data from production as well as post-production activities.

Information gathered in the feedback process shall server as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement process.

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

8.2.2. Complaint Handling

A-M Systems maintains documented procedures for timely complaint handling in accordance with applicable regulatory requirements.
These procedures include at a minimum requirements and responsibilities for:

- Receiving and Recording Information
- Evaluating information to determine if the feedback constitutes a complaint.
- Investigating complaints
- Determining the need to report the information to the appropriate regulatory authorities.
- Handling of complaint-related product
- Determining the need to initiate corrections or corrective actions

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained as per paragraph 4.2.5, Control of Records.

8.2.3. Reporting to Regulatory Authorities

The organization maintains a documented procedure for providing applicable regulatory authorities with notifications of complaints where such complaints meet specified reporting criteria or adverse events or issuance of advisory notices.
Regulatory reporting records will be maintained as per paragraph 4.2.5, Control of Records.

8.2.4. 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.
- Health Canada CMDR
- EU MDR
- The planned arrangements following paragraph 7.1, Planning of Product Realization
- The requirements of the ISO 13485:2016 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 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 4.2.5, Control of Records.

Supporting Procedure: Q:\QSP\QSP-8.2.4 Internal Quality Audits.pdf

8.2.5. 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 4.2.5, Control of Records.

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

8.2.6. Monitoring and Measurement of Product

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.
- As appropriate, records shall identify the test equipment used to perform measurement activities.

Supporting Procedure: Q:\QSP\QSP-8.2.6 Monitoring and Measurement of Product.pdf

8.3. Control of Nonconforming Product

8.3.1. General

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.

The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, and any investigation and rationale for decisions shall be maintained as per paragraph 4.2.5, Control of Records.

8.3.2. Actions in Response to Nonconforming Product Detected Before Delivery

A-M Systems shall deal with nonconforming product by one of the following ways:

- Taking action to eliminate the detected nonconformity.
- Taking action to preclude its original intended use or application.
- Authorizing its use, release, or acceptance under concession.

When nonconforming product is accepted by concession, justification must be provided, approval must be gained, and applicable regulatory requirements must be met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained as per paragraph 4.2.5, Control of Records.

8.3.3. Actions in Response to Nonconforming Product Detected After Delivery

When nonconforming product is detected after delivery or use has started, A-M Systems shall act appropriate to the effects, or potential effects, of the nonconformity. Records of these actions are maintained as per paragraph 4.2.5, Control of Records.

The company maintains a procedure for guidance on issuing advisory notices in accordance with applicable regulatory requirements. This procedure is capable of being put into effect at any time as certain regulatory authorities require reporting to be done as per their published timelines. Records relating to the issuance of advisory notices are maintained as per paragraph 4.2.5, Control of Records.

8.3.4. Rework

The company performs rework in accordance with documented procedures that considers the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.

When rework is completed, the reworked product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework shall be maintained as per paragraph 4.2.5, Control of Records.

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

Supporting Procedure: Q:\QSP\QSP-8.1 Regulatory Bodies.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 procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data provides, at a minimum, information relating to:

- Feedback.
- Customer satisfaction.
- Conformity to product requirements.
- Characteristics and trends of processes and products, including opportunities for improvement and preventive actions.
- Supplier performance and suitability.
- Audits.
- Service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate, or effective, the analysis shall be used as input for improvement as per paragraph 8.5, Improvement.

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

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 using 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 acts, when necessary, to eliminate the cause of nonconformities to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered and shall be taken without undue delay. Corrective actions shall be proportionate 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 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.
- Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
- Review and monitor the effectiveness of any corrective action(s) that are taken.

Records with results of action taken are maintained per paragraph 4.2.5, Control of Records.

Supporting Form: Q:\QSP\QSP-8.2.2 Complaint Handling.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

8.5.3. Preventive Action

A-M Systems acts, as appropriate, to eliminate the causes of potential nonconformities 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.
- Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
- Monitor and review any preventive action taken and its effectiveness.

Records of the preventive action are maintained per paragraph 4.2.5, Control Of Records.

Supporting Form: Q:\QSP\QSP-8.2.2 Complaint Handling.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