Quality Manual

AMERICAN DIAGNOSTIC CORPORATION

Quality Manual

Section 1: Quality Management System

1.1 General Requirements

1.1.1 Executive Management has established, maintains, and continuously improves a documented Quality Management System in order to meet the requirements of the ISO 13485:2016 Standard, EN ISO 13485:2016 Standard, Annex V of Directive 93/42/EEC and the Medical Device Regulation of the European Union, the medical device regulations of Canada, Australia, Japan, and the Quality System Regulations of the FDA.

1.1.2 As the business scope of American Diagnostic Corporation expands to encompass new countries and regions; the Quality Management System will be updated to incorporate any regulatory requirements mandated by the governments of these countries/regions. The Quality Management System will also be continually improved for effectiveness in accordance with the previously referenced standards and regulations, with the goal of this improvement being increased product quality, process efficiency, and customer satisfaction.

1.1.3 Executive Management has:

a) Identified the processes needed for the Quality Management System and their application throughout the organization (as required by the referenced standards and regulations stated previously, and by the roles ADC has identified discussed in the sections below)
b) Applied a system of risk-based thinking to approach the control of processes required for the Quality Management System
c) Determined the sequence and interaction of these processes (Note: refer to the ADC process flowchart in this Quality Manual for a basic overview of the processes within ADC.)
d) Determined criteria and methods needed to ensure that both the operation and the control of these processes are effective based on the risks associated with these processes
e) Ensured the availability of resources and information necessary to support the operation and monitoring these processes, including the development of appropriate departments to handle defined responsibilities as part of the Quality Management System
f) Developed systems to monitor, measure, and analyze these processes

g) Implemented processes necessary to achieve planned results and developed systems to monitor and provide for continual improvement of these processes.
h) Developed record keeping requirements to demonstrate conformity of the defined processes both with ADC's Quality Management System as well as the national and international regulations described previously.

1.1.4 Processes are managed in accordance with Standard Operating Procedures (SOPs), work instructions, and other documents developed to meet the requirements of the previously referenced national and international standards.

1.1.5 Below is a flow chart depicting ADC's Quality Management System. This flowchart provides a brief overview of the interaction of various processes that make up the entire Quality Management System. The flowchart also demonstrates how customer and regulatory requirements and feedback from customers and regulatory authorities play a role in ADC's Quality Management System.

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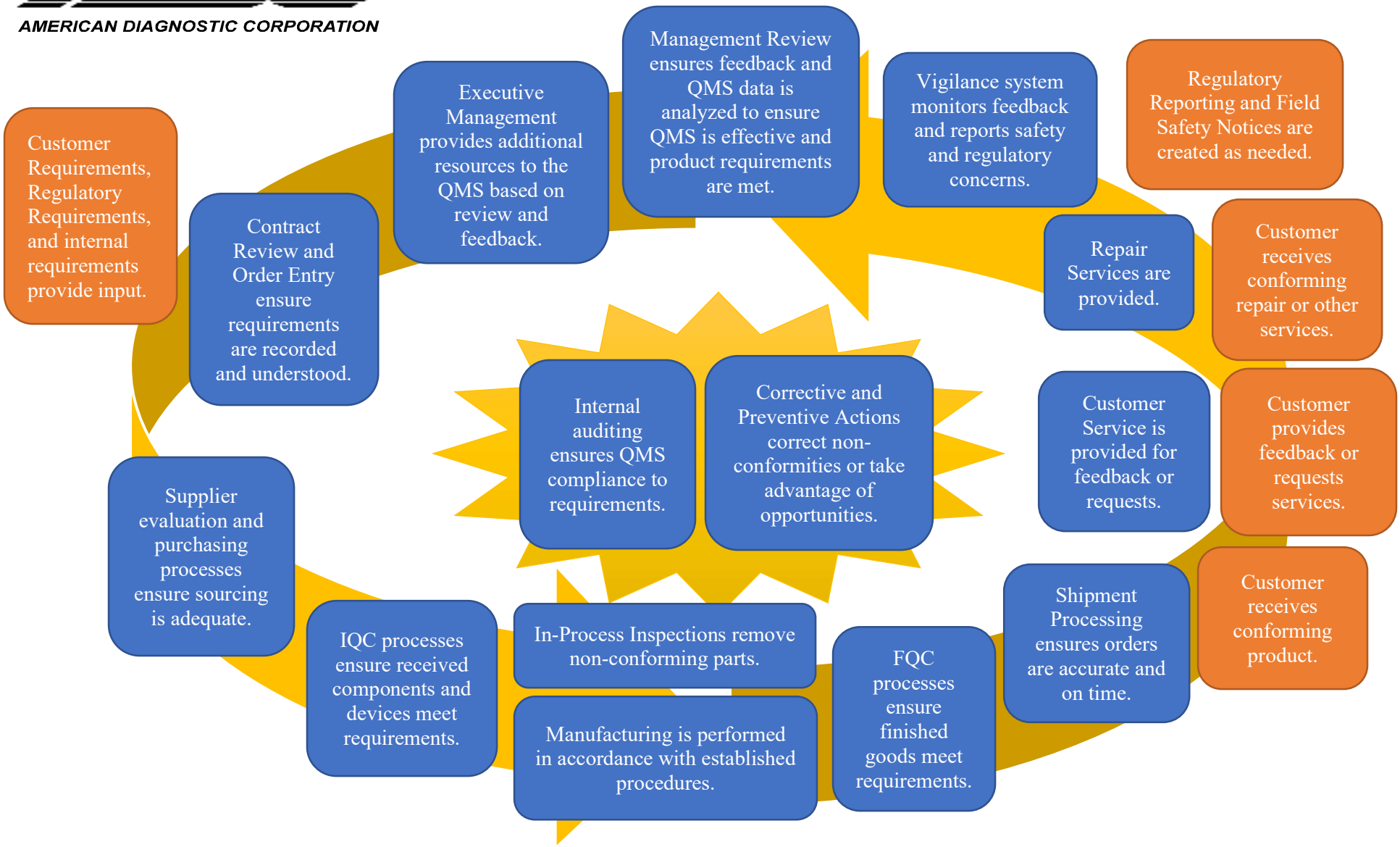

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1.1.6 As new products are developed or new customer and regulatory requirements come into effect, processes will be designed to incorporate these new requirements. These new processes will fit into the process flow as illustrated above.

1.1.7 All processes that make up the Quality Management System are interconnected, with the output of one process becoming the input for the following process. This process flow ensures that customer and regulatory requirements are met throughout the creation of products and services.

1.1.8 Where processes that might affect product quality are performed through outsourcing, Executive Management has established processes to ensure that product quality is maintained and that products conform to requirements.

1.1.9 This Quality Manual is intended to describe ADC's Quality Management System in detail, and to encompass the roles encompassed by ADC's business practices. These roles include all the following:

- Importation into the United States of components, parts, accessories, and finished medical devices from a global supply chain.
- Inspection, manufacturing, packaging, labeling, and relabeling of medical devices.
- Sale and distribution of medical devices to medical device distributors (note: this role does not include direct retail sales or direct-to-user sales of medical devices).
- Global exportation of medical devices to those countries where ADC conducts business.

1.1.10 Changes to processes within ADC's QMS are evaluated prior to implementation as described in the Standard Operating Procedures. Changes are controlled to ensure that they will not have an adverse impact on the QMS or on medical devices produced within ADC's QMS. Change control records are maintained demonstrating conformity of the change process and of the changes made to individual work instructions or documents.

1.1.11 ADC's defined roles and manufacturing model involve the use of outsourced processes. In order to ensure conformity to requirements, suppliers of outsourced processes are evaluated for competency and qualifications to perform these processes dependent upon the risk associated with the processes or devices being provided. As part of the QMS, ADC retains supplier agreements and maintains a robust inspection process to ensure that the outputs of outsourced processes are compliant with requirements.

1.1.12 As some portions of the Quality Management System may involve the use of automation or computer software, such software will be included in a validation process to control the deployment and application of software and ensure that it is suitable for its intended use. These processes will be discussed through various Standard Operating Procedures and work instructions.

1.2 Documentation Requirements

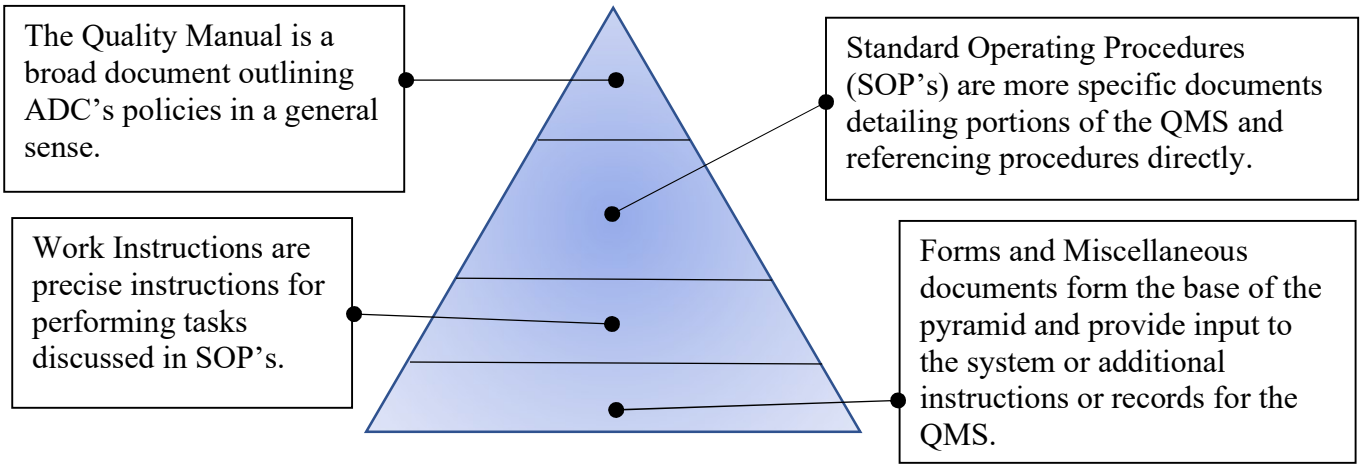
1.2.1 The Quality Management System is documented and includes a Quality Policy and Quality Objectives, a Quality Manual, documented procedures, internal documents, and Quality Records. These documents ensure that all processes are effectively planned, implemented, and controlled and are tiered as discussed in previous sections of this manual.

1.2.2 As part of the Quality Management System documentation, all documents and files that are required by various regulatory authorities have been created and are maintained in physical or electronic form. These documents include, but are not limited to, the following:

- Device Master Records (DMR)
- Production History Reports
- Product Technical Files (TFCE)
- Adverse Event Reports
- Complaint Files

1.2.3 All documents and files that are required by various regulatory authorities are discussed throughout ADC's Standard Operating Procedures and work instructions. As new requirements become mandatory, additional work instructions will be created to outline the steps that ADC will take to satisfy those requirements.

1.2.4 Documents that make up the Quality Management System are arranged in tiers, with this Quality Manual representing the broadest, generalized document. Standard Operating Procedures are associated with this Quality Manual and make reference to it, but contain more detailed information. Work instructions provide precise, step-by-step instructions and make reference to the SOP's. This tiered structure is described in greater detail in specific work instructions. The documentation for the Quality Management System is thus developed as a pyramid, as depicted in the image below:



1.3 Quality Manual, Quality Management System Exclusions and References

1.3.1 This Quality Manual includes:

- The scope of the Quality Management System, including details of and justification for any exclusions,
- References to the documented procedures established for the Quality Management System,
- A description of the interaction between the processes of the Quality Management System as detailed in previous sections.

1.3.2 This Quality Manual has been designed as a general guidance on, and description of, ADC's Quality Management System. It is intended for general distribution to external sources.

1.3.3 EXCLUSIONS AND NON-APPLICABLE SECTIONS

1.3.3.1 This section defines sections that ADC is excluding from the Quality Management System as well as sections that are not applicable to ADC's Quality Management System at this time. These exclusions and non-applicable sections may be included in the Quality Management System in the future should ADC's business practices or product line change in such a way that warrants their inclusion. New products and new processes will be evaluated by Executive Management to determine if changes to the Quality Management System would be necessary in relation to these exclusions.

1.3.3.2 The following points are excluded or non-applicable in relation to ADC's Quality Management System. A brief discussion of the justification for each exclusion is included along with the points.

Topic:	**Justification:**	**Excluded EN ISO 13485:2016 Sections:**
Sterility	As discussed in sections 4.6.2 and 4.9 of this manual, ADC does not currently manufacture any devices that are provided to the customer in a sterile state. National and international requirements relating to this topic are not applicable to ADC at this time.	6.4.2 (paragraph 2 only), 7.5.5, 7.5.7
Installation and Maintenance (Note: service/repair is not excluded)	As discussed in sections 4.7 and 4.8 of this manual, ADC does not install any medical devices. Maintenance activities performed by ADC are limited to those activities that are performed within ADC's own facility; no maintenance activities are performed at customer owned facilities. The Quality Management System therefore will not include processes for installation or maintenance in customer owned facilities.	4.2.3(e), 7.5.3
Implantable and Active Implantable Medical Devices	As discussed in sections 4.11.5 and 5.5.4, ADC does not manufacture or distribute implantable or active implantable medical devices. Any national or international requirements for these device types are not applicable to ADC's Quality Management System at this time.	7.5.9.2, 8.2.6 (last sentence only)
Life Supporting and Life Sustaining Devices	ADC does not manufacture life supporting or life sustaining devices where device tracking requirements may be applicable.	This topic is not specifically referenced in EN ISO 13485:2016 but may be referenced in other regulations applied in this Quality Manual.
Design and Development	ADC does not perform design functions, and our modifications to products are limited to selection of colors and packaging artwork. ADC uses global vendors to develop components or complete devices for our product line.	7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7, 7.3.8, 7.3.9, 7.3.10

1.3.4 MEDICAL DEVICE FILE

1.3.4.1 As part of the documentation included within ADC's Quality Management System and defined in this Quality Manual, a Medical Device File is created for each medical device type or medical device family produced by ADC.

1.3.4.2 ADC's Medical Device File is referenced in SOP 4.0, *Quality Management System,* which describes how these files are created and where individual portions of the file are made within the QMS.

1.4 Control of Documents

1.4.1 Executive Management has established a document control system to ensure that documents required by the Quality Management System are controlled. They cannot be adjusted or modified by any ADC personnel without authorization.

1.4.2 Quality Records are maintained as indicated in specific work instructions. They are controlled and stored for at least the lifetime of ADC's products, as defined in technical files (TFCE) and other documents. This applies to obsolete revisions of documents as well as active documents that are in use.

1.4.3 Executive Management has established and maintains a documented procedure to define the controls needed:

- To review, approve, and ensure the adequacy of documents before their release for use
- To update documents as they become obsolete or require correction, including a review and approval process for these updates
- To ensure that changes and the current revision status of documents are identified
- To ensure that documents are distributed to the appropriate personnel and that they are available as needed
- To ensure that documents remain legible and readily identifiable
- To ensure that documents of external origin are identified and their distribution controlled where these documents could impact the company's Quality Management System
- To prevent the unintended use of obsolete documents by preventing their distribution, and ensuring that any obsolete documents retained for reference purposes are clearly marked "obsolete"

1.4.4 Document control will be performed in accordance with SOP 4.0, *Quality Management System*. This SOP makes reference to or describes the procedures used to approve and review documents, as well as discussing document retention and the requirement that document deterioration be prevented with appropriate storage.

1.4.5 As part of the document control system established by Executive Management, the process for changing existing documents and the requirements for the review of these revised documents have been established to ensure that a competent review is performed that results in proper document revision.

1.5 Control of Quality Records

1.5.1 As part of the various processes and procedures that make up ADC's Quality Management System, Quality Records will be generated where appropriate to ensure that proper documentation and record keeping is performed when vital processes are completed. Quality Records are created and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. These records will remain legible, readily identifiable, and retrievable.

1.5.2 Documented procedures have been established as part of the Quality Management System that define the controls needed to create and maintain Quality Records. These procedures define the processes used for identification, storage, protection, retrieval, retention time, and disposition of quality records. These procedures are included in various work instructions that apply to the departments that produce these records and the records will be directly referenced in these departmental work instructions.

1.5.3 Quality records are controlled in accordance with SOP 4.0, *Quality Management System*. Quality Records are maintained for the lifetime of each medical device as defined in the technical documentation for that device or for a period of at least five years if the expected lifetime of a medical device is less than this time. (Note: Most medical devices manufactured by American Diagnostic Corporation have a life cycle of less than five years.)

1.5.4 Where confidential health data is collected within ADC's records, such information will be handled in accordance with SOP 4.0, *Quality Management System* to ensure that such data is protected and kept confidential.

1.5.5 Where records are changed or modified, these changes must be performed in accordance with SOP 4.0, *Quality Management System,* to ensure that changes are identifiable.

Section 2: Management Responsibility

2.1 Management Commitment

2.1.1 Executive Management has demonstrated a commitment to the development and implementation of the Quality Management System, and continually improving its effectiveness by:

- Communicating to the Company the importance of meeting Customer requirements (in particularly, requirements for safety and performance of ADC devices) through documented procedures, newsletters, and posted policies
- Reviewing statutory and regulatory requirements and news through Management Review and internal newsletters and documents
- Establishing the Quality Policy (Refer to the sections below for more details)
- Establishing Quality Objectives that are meaningful to ADC's business model, and reviewing these measurable objectives on a regular basis (through Management Review) to ensure that they help to improve ADC's overall quality
- Conducting Management Reviews
- Providing the resources needed by the Quality Management System to ensure its proper operation by reviewing resource needs and providing systems to allow for the acquisition of additional resources as necessary

2.1.2 Management commitment is addressed in SOP 5.0, *Management Responsibility*, and is also documented in a variety of work instructions that form the Quality Management System.

2.2 Customer Focus

2.2.1 Executive Management will ensure that Customer requirements are determined and fulfilled with the aim of enhancing Customer Satisfaction while meeting regulatory requirements. Through ADC's contract review process all customer orders and extended contracts are reviewed to ensure that ADC can meet all the customer's requirements, both stated and unstated.

2.2.2 To ensure that customers are satisfied throughout the lifetime of their purchases, ADC's Customer Service Department has been established to provide customers with the services they need. Customers can purchase ADC products with the knowledge that ADC's Customer Service Department will be available with technical support, order information, and to help the customer obtain repairs as necessary.

2.2.3 Customer focus is addressed in SOP 5.0 *Management Responsibility*, and is also documented in a variety of work instructions that form the Quality Management System.

2.3 Quality Policy

2.3.1 Executive Management will ensure that the Quality Policy is appropriate to the roles and activities outlined in this Quality Manual and in ADC's Quality Management System, includes a commitment to comply with the requirements of both customers and regulatory authorities and a commitment to continually improve the effectiveness of the Quality Management System.

2.3.2 The Quality Policy will provide a framework for establishing and reviewing Quality Objectives as all Quality Objectives are designed to conform to the basic principles presented in the Quality Policy. Executive Management will ensure that the Quality Policy is communicated and understood throughout ADC, and will review the Quality Policy for adequacy and suitability through mechanisms such as Management Review and regular management meetings.

2.3.3 The Company Quality Policy is:

"The Company is committed to maintaining the effectiveness of, and continually improving, our Quality Management System to respond to and meet the expectations of our Customers while remaining in compliance with the legal requirements of the markets we serve."

2.3.4 It is important to note that the above quality policy discusses *maintaining* the Quality Management System. The use of the word *maintaining* is taken to mean not only the maintenance of the existing system, but ensuring that the system is maintained in accordance with the requirements of applicable regulatory authorities. This policy ensures that ADC's Quality Management System meets not only the requirements of our customers, but also all legal requirements in the countries where ADC conducts business.

2.3.5 In addition to the above interpretation, it is also important that the word "*customers"* is defined. When the customer is referred to in any documentation relating to ADC's Quality Management System, any of the following could apply:

- The distributor, retailer, or reseller that directly purchased the product.
- The end user, including the doctor, nurse, and the healthcare institution using the device, or the home user.
- The patient that the device is being used on.

2.3.6 This definition of customer ensures that all safety and reliability concerns are addressed as part of ADC's Quality Management System.

2.3.7 The Quality Policy is addressed in SOP 5.0 *Management Responsibility*, and is also documented in a variety of work instructions that form the Quality Management System.

2.4 Planning

2.4.1 QUALITY OBJECTIVES

2.4.1.1 Executive Management has established Quality Objectives at relevant functions and levels within the Company. These Quality Objectives are measurable and consistent with the Quality Policy. (Note: Quality Objectives include objectives created for ADC products that measure quality and other characteristics of ADC's level of service.)

2.4.1.2 Quality Objectives are reviewed by Executive Management during the normal Management Review process. This ensures that progress towards these goals can be monitored, and the Quality Objectives can be revised as necessary to more appropriately match the resources and capabilities of ADC's various departments.

2.4.1.3 The Quality Objectives are addressed in SOP 5.0 *Management Responsibility*.

2.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

2.4.2.1 Executive Management will ensure that the planning of the Quality Management System is carried out in accordance with the national and international standards referenced earlier in this manual, as well as the Quality Policy. Executive Management will also ensure that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

2.4.2.2 The Quality Management System, and any changes that will be made to the Quality Management System, will be reviewed during normal Management Review Meetings prior to implementation. This will ensure that the integrity of the Quality Management System is maintained at all times.

2.4.2.3 Changes to existing processes or the creation of new processes will also be discussed during Plant Manager Meetings. These meetings provide Executive Management with an appropriate forum to discuss impending changes to the Quality Management System. Changes to existing processes can be planned out prior to implementation, with Executive Management available to provide guidance.

2.4.2.4 Quality Management System planning is performed in accordance with SOP 5.0 *Management Responsibility*.

2.5 Responsibility, Authority, and Communication

2.5.1 RESPONSIBILITY AND AUTHORITY

2.5.1.1 Executive Management has defined and documented the responsibility, authority, and the interrelation of personnel who manage, perform, and verify work within the Quality Management System. Part of this documentation includes official job descriptions, which define the various tasks performed by employees during their daily activities.

2.5.1.2 Executive Management has developed the *ADC Organizational Chart* that depicts the quality organization. This organizational chart includes official job titles and shows the interrelation of all ADC employees. It is further addressed in SOP 5.0, *Management Responsibility*.

2.5.2 MANAGEMENT REPRESENTATIVE

2.5.2.1 Executive Management has appointed the *Quality Manager* as the Management Representative for the Quality Management System. The Management Representative has the responsibility and authority that includes:

- Ensuring that processes needed for the Quality Management System are established, implemented, and maintained by making use of resources provided by Executive Management and personnel from various departments within the company

- Reporting on the performance of the Quality Management System to Executive Management and any need for improvement (Note: this reporting is aided by the analysis of quality system data obtained through normal monitoring and measurement processes.)
- Ensuring the promotion of awareness of Customer requirements throughout the Company
- Ensuring the awareness of regulatory requirements and QMS requirements throughout the company through the use of policies, internal newsletters, and other methods of communication.

2.5.2.2 Appointment of the Management Representative is addressed in SOP 5.0, Management Responsibility. An official job description has been created to describe all the functions and responsibilities of the *Quality Manager* in relation to his or her duties as the Management Representative.

2.5.3 INTERNAL COMMUNICATION

2.5.3.1 Executive Management has established communication processes within the Company to ensure that processes included as part of the Quality Management System are effectively implemented and maintained. This communication ensures that the Quality Management System is effective and accomplishes stated objectives.

2.5.3.2 This communication process makes use of all computerized resources that are available at ADC, and includes the creation and continuous adaptation of an electronic Information System to provide all departments with the latest information, controlled documents, and Quality Objectives.

2.5.3.3 Responsibility, authority, and communication are addressed in SOP 5.0, *Management Responsibility*.

2.6 Management Review

2.6.1 Executive Management will conduct a review of the Quality Management System on a periodic basis to ensure its continued suitability and effectiveness in accordance with the Quality Policy and Quality Objectives. This review will include assessing opportunities for improvement and the need for changes to the Quality Management System, including the Quality Policy and Quality Objectives. The Management Review meeting will be attended by a variety of management staff throughout ADC to ensure that all relevant information is presented and reviewed, and will include the results of analysis of data collected throughout the organization.

2.6.2 The input to Management Review will be in the form of a report. This report is prepared using quality system data collected through monitoring and measurement processes, as well as statistical data obtained during analysis. This report includes:

- Results of audits
- Customer feedback information and specifically, customer complaints
- Process performance and product conformity information (from a variety of sources)
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the Quality Management System
- Recommendations for improvement
- New or updated regulatory requirements
- Regulatory reporting, field safety notices, or other key communications with regulatory authorities

2.6.3 The output from Management Review includes any decisions and actions related to:

- Improvement of the effectiveness of the Quality Management System and its processes
- Improvement of product related to Customer requirements
- Resource needs
- Corrective and preventive actions as applicable
- Improvements to the QMS that may be necessary to ensure its continued suitability and adequacy
- Changes made to address new regulatory requirements or to respond to changes made to regulatory requirements

This output will be presented in a form that is suitable for the various departments it may affect. Policies created during normal management review will be incorporated into existing work instructions and procedures where appropriate, or documented in new procedures where required.

2.6.4 Management Review is performed in accordance with SOP 5.0, *Management Responsibility*. Management Review is documented in separate work instructions that further detail the various inputs and the outputs that are achieved by this meeting.

Section 3: Resource Management

3.1 Provision of Resources

3.1.1 Executive Management has determined and provided the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness. These resource requirements are reviewed during normal management review to ensure that they are adequate for all of ADC's various departments.

3.1.2 Executive Management has provided the resources necessary to enhance Customer Satisfaction by meeting customer requirements as well as all applicable regulatory requirements for ADC's products and services.

3.1.3 Systems have been created internally to allow for the acquisition of additional resources by internal departments to help address ongoing needs and support the Quality Management System.

3.1.4 Provision of resources is addressed in SOP 6.0, *Resource Management,* and is also documented in a variety of work instructions that form the Quality Management System.

3.2 Human Resources

3.2.1 Personnel performing work affecting the quality of ADC's products or services will be competent based on appropriate education, training, skills, and experience. Executive Management has established a Human Resources Department to organize the process of hiring new employees.

3.2.2 ADC's training process:

- Determines the necessary competence for personnel performing work affecting product quality (This information is included in relevant job descriptions and training plans developed under ADC's training system.)
- Provides training or takes other actions to satisfy these needs, documenting the training through ADC's Training System
- Evaluates the effectiveness of actions taken through regular, risk based training effectiveness checks that are documented through ADC's Training System

- Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives. This is accomplished through incentive programs, training sessions, and the appropriate communication of the Quality Policy and Quality Objectives.
- Includes ADC's Training System that maintains appropriate records of education, training, skills, and experience

3.2.3 Human resources are addressed in SOP 6.0, *Resource Management.* This topic is also documented in a variety of work instructions that form the Quality Management System. This documentation includes official job descriptions, which contain the educational and training requirements needed to perform specific tasks.

3.3 Infrastructure

3.3.1 Executive Management has provided and maintains the infrastructure needed to achieve conformity to product requirements as well as to ensure proper product handling to avoid mix-ups and non-conformities. Infrastructure includes:

- Building, workspace, and associated utilities
- Process equipment, including hardware and software associated with this equipment
- Supporting services such as transport or communication
- Telephone communication systems, computers, network equipment, computer backup equipment, and associated databases
- Internally developed software for product or QMS management
- Test equipment

3.3.2 As part of Executive Management's commitment to provide adequate infrastructure a dedicated IT Department has been created to safeguard all electronic data and ensure the uninterrupted operations of ADC's computer systems.

3.3.3 Where equipment maintenance is required to ensure continued functionality of ADC equipment or utilities, such maintenance has been included in work instructions applicable to specific pieces of equipment. Maintenance may include calibration and inspection as appropriate.

3.3.4 For those processes that affect product quality, Executive Management has established documented work instructions and procedures to ensure that any equipment that can have an impact on product quality is maintained in an adequate fashion.

3.3.5 Infrastructure is discussed in more detail in SOP 6.0, *Resource Management*. Additional information pertaining to inspection and test equipment can also be found in SOP 7.0, *Product Realization.*

3.4 Work Environment

3.4.1 Executive Management has established the work environment criteria needed to achieve conformity to product requirements. These criteria include procedures and processes for building cleanliness, process efficiency, and employee safety.

3.4.2 Where the health, cleanliness, or clothing of ADC personnel could adversely affect the quality and/or safety of ADC's products, criteria have been established to ensure product quality.

3.4.3 Any products produced by ADC that could be adversely affected by environmental conditions will be protected to ensure that product quality and safety does not suffer. Environmental controls necessary to safeguard these products will be documented and maintained as appropriate.

3.4.4 Where environmental controls are necessary, the training and skill of employees working in these controlled areas will be documented to ensure the safety of both the employees as well as ADC products.

3.4.5 Executive Management has established a Safety Committee to ensure that relevant employee safety issues are discussed and resolved. This committee is responsible for overseeing all aspects of employee safety, including the handling and/or storage of any hazardous materials.

3.4.6 As part of the procedures and documents created to control the cleanliness and work environment of ADC, contamination (with hazardous OR non-hazardous materials) of product will be controlled to prevent the spread of contamination to other products, the environment, or ADC employees.

3.4.7 ADC does not manufacture sterile medical devices, but should such devices become part of ADC's product line, processes would be created directly to address cleanliness and contamination control for such devices to ensure continued sterility.

3.4.8 Work environment is addressed in SOP 6.0, *Resource Management*, and is also documented in a variety of work instructions that form the Quality Management System.

Section 4: Product Realization

4.1 Planning of Product Realization

4.1.1 Executive Management plans and develops the processes needed for product realization. These processes include the steps necessary to introduce new products, as well as the implementation of procedures and work instructions to detail the processes used to create and inspect the products. Planning of product realization is consistent with the requirements of the other processes of the Quality Management System and includes any services provided by ADC to our customers.

4.1.2 ADC's Quality Management System includes a risk management system that ensures that risk-based thinking is applied throughout our organization. Risk management is applied to product realization in both the introduction of products prior to initial production as well as during the development or change of procedures and processes that make up the QMS. Risk assessment has been applied to ADC's QMS to identify risks and opportunities throughout our organization. Records of risk analysis are maintained as Quality Records.

4.1.3 When planning product realization, Executive Management determines and documents the following, as appropriate:

- Quality Objectives and requirements for the product which are described in product Device Master Records and associated stand-alone work instructions (In particularly regulatory requirements for the various regions that the product will be sold in.)
- The need to establish processes, documents, and provide resources specific to the product
- Required verification, validation, monitoring, inspection, measurement, and test activities specific to the product and the criteria for product acceptance as defined in ADC's IQC, In-process, and FQC processes. This includes, as appropriate, any necessary training for inspection personnel.
- Records needed to provide evidence that the realization processes and resulting product fulfill requirements
- Infrastructure needed for a product including equipment, utilities, facility requirements, etc.
- Work environments needed for a product including controlled environments, requirements for sterility, etc.
- Handling and storage requirements where applicable to the product being developed or introduced

- Distribution and traceability requirements as applicable to the type of product being developed or introduced

4.1.4 It is important to note that included within the requirements for a product are all technical/regulatory documentation requirements that ADC must meet in order to market a product, as well as post-market activities and product disposal where applicable.

4.1.5 Executive Management has established appropriate communication processes and/or committees to ensure that all relevant information relating to product development and the planning of product realization is discussed and presented to every department of ADC prior to implementation. This includes the use of a Product Meeting to coordinate the introduction of new products.

4.1.6 The output from product realization planning includes all the forms, work instructions, technical documentation, and other records associated with the development of products and processes. These materials are incorporated into ADC's Quality Management System.

4.1.7 Additional information about the planning of product realization is available in SOP 7.0, *Product Realization*.

4.2 Customer Related Processes

4.2.1 Executive Management has created a contract review system employed by ADC's Customer Service Department and sales force that ensures customer requirements are understood prior to accepting an order. The purpose of this system is to ensure order accuracy and reduce errors when customers place orders. This system also ensures that specific contracts are reviewed appropriately before acceptance. This system has been designed to determine:

- Requirements specified by the Customer, including the requirements for delivery and post-delivery activities
- Requirements not stated by the Customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Any training needs for the specific product being sold (In most cases, the type of devices manufactured by ADC do not have additional training requirements, but such requirements will be addressed should product lines requiring them be introduced.)

- Any additional requirements necessary to ensure the customer's satisfaction, such as providing technical information or specific documentation

4.2.2 Executive Management has created a contract review system to review the requirements related to the product. This review will be conducted prior ADC's commitment to supply a product to the Customer and will ensure that:

- Product requirements are defined and documented in physical form or using electronic systems. In most cases ADC customers will purchase existing ADC products as defined and documented in ADC's catalog. When new products are proposed, the requirements will be documented through ADC's product support team.
- Contract or order requirements differing from those previously expressed are resolved (Ex: pricing, part numbers)
- Applicable regulatory requirements are met (Ex: products with regional restrictions are not sold in areas where they are not available.)
- Training is provided where this is a requirement for the sale of the product (Note: ADC's current product offerings do not include products that require additional training. Such requirements will be addressed during product realization where it is determined that a new product will have training requirements for the end user.)
- ADC's current products (or proposed new products) meet the defined requirements, including the requirements for quantity as appropriate

4.2.3 Records of the results of contract review and actions arising from the review will be maintained as Quality Records and are available to appropriate departments so that revisions to existing contracts can be evaluated before implementation. (Ref. SOP 7.0, *Product Realization*)

4.2.4 In instances where a customer provides no documented statement of requirements, the customer requirements will be confirmed by ADC's Customer Service Department prior to the acceptance of any orders as part of the contract review process. Where product requirements are changed, ADC will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements as appropriate. Where customers are ordering standard ADC parts, the customer may only alter product requirements as defined in ADC's written work instructions. Reference SOP 7.0, *Product Realization* for more information pertaining to contract review and custom orders.

4.2.5 As part of the process of reviewing customer requirements, ADC conducts regular reviews of catalogs and product information that is provided to the public. This review ensures a continual improvement and clarification of relevant product information. In particular, this information is reviewed as part of the product realization process to ensure product specifications and information is available relating to new products or product changes.

4.2.6 Executive Management has implemented effective arrangements for communicating with Customers in relation to:

- Product information, including technical details about ADC's products, sales information, and service information.
- Inquiries, contracts, or order handling, including amendments
- Customer feedback, including customer complaints

4.2.7 Executive Management has established a documented system to ensure that customers are aware of advisories or recalls that apply to ADC products. This ensures end-user safety by allowing for the quick distribution of information relating to problems associated with a particular device or batch of devices.

4.2.8 ADC's Quality Management System includes provisions for reporting product safety or other issues to regulatory authorities as applicable to the regions ADC serves.

4.2.9 Customer related processes are further addressed in SOP 7.0, *Product Realization*. Additional details pertaining to ADC's vigilance system may also be located in SOP 4.0, *Quality Management System.*

4.3 Design and Development

4.3.1 American Diagnostic Corporation does not engage in direct design and development activities for our products. Instead product development is limited to the section of off-the-shelf or custom made parts provided by our supply chain, as well as the selection of colors and packaging options. Executive Management has developed the procedures necessary to document the process of bringing new products to market and the details of this process are discussed below.

4.3.2 These procedures include a system that manages the interfaces between different groups involved in bringing new products to market to ensure effective communication and clear assignment of responsibility for various elements of this process. Documentation will be updated, as appropriate, as a product nears launch date.

4.3.3 ADC maintains product development project files, ensuring that a complete history of a product's development is available for review.

4.3.4 During the planning phase of new product introduction, product requirements will be determined, and appropriate suppliers selected. These inputs will form the basis for a product development project file for that product or product line. These files will include information pertaining to functional, performance, usability, and safety requirements as applicable, any regulatory requirements that apply to the product, other requirements essential for production of the product, including ADC specifications or components lists as applicable, as well as measurement/inspection requirements that may indicate the need for new measurement procedures/techniques, risk assessment information as applicable and finally, post market activities as applicable to the product (including servicing and product disposal)

4.3.5 Product requirements and specifications are reviewed by assigned personnel after they have been determined to ensure that they are adequate and that they meet ADC's objectives for marketing the product. Throughout the process of introducing a new product, reviews are conducted by relevant departments to ensure that the implementation of processes during product realization meets all stated requirements.

4.3.6 Where requirements are found to be incomplete, ambiguous, or in conflict with one another, these requirements will be clarified and corrected before any product is manufactured or processes are implemented. It is important to note that products must be verified and validated prior to introduction, and this may be performed by ADC's established subcontractors or through internally developed reports as appropriate to the type of product being introduced.

4.3.7 ADC will maintain, or will indirectly maintain through contracts with select subcontractors, all relevant information necessary to verify that the product meets all stated requirements. This includes documents and records that cover some or all of the following:

- The ability of the product to meet stated requirements
- Provide adequate information for purchasing, production, and service provision as well as adequate information for storage, handling, or other factors such as environmental requirements
- Contain or reference product acceptance criteria, including information for IQC, In-Process, and FQC inspections
- Contain or reference product safety specifications and other factors essential for its safe and appropriate use.

4.3.8 During the introduction of a new product, the relevant work instructions, forms, procedures, and other documentation will be created to ensure that purchasing, production, customer service, quality control, and service processes are established. Documentation related to the safety and performance characteristics of the product will also be established where appropriate.

4.3.9 Gathered product information ensures that the selected product will meet requirements. The methods of verification, acceptance criteria, and sample sizes (including statistical rationale for sample sizes selected where appropriate) will be included as part of the product realization process. Verification also includes, where appropriate, verification that the product works when connected to devices that it was designed to work in conjunction with.

4.3.10 ADC's product selection process will ensure that products are validated prior to selection for marketing. This validation is conducted on representative product or components to ensure that the final product is able to meet all of the performance and safety requirements for the intended use/application of the product. This validation may be performed by ADC's subcontractors or in our facility using appropriate test equipment depending on the contractual obligations of the product. Validation will include testing the product with connected devices when products are designed to be used in conjunction with other medical devices.

4.3.11 Clinical validation or clinical literature research will be conducted in accordance with national and international regulations for new products. These activities may be performed by ADC directly or by contracted subcontractors as appropriate for the product line and relevant technical capabilities of ADC and its suppliers.

4.3.12 Executive Management has established a product communication system that includes written documents and Product Meetings to ensure products are thoroughly reviewed and evaluated prior to introduction.

4.3.13 Product Meetings will include Executive Management as well as members of ADC's product support team to ensure that all aspects of the product specifications are properly communicated to those departments that require specific information. Records of all Product Meetings are retained as Quality Records.

4.3.14 As part of ADC's product management process, changes to existing products are reviewed for significance, assessed for risk, verified, and validated before they are approved and implemented. This review will ensure that the finished product, as well as components for the product will continue to function as intended.

4.3.15 After the introduction of a new product has been determined, the product specifications are transferred to manufacturing and to other relevant departments to allow for full production to commence. The process of transferring these product specifications is documented.

4.3.16 The introduction of a new product is documented within individual Design History Files. Additional procedures and processes for product development can be found in SOP 7.0, *Product Realization,* and throughout ADC's Quality Management System.

4.4 Purchasing

4.4.1 Executive Management has established a Quality Control Department to ensure that purchased product conforms to specified purchase requirements. All products and components arriving at ADC are inspected and tested to verify the quality of each shipment. Inspection requirements are based on how critical purchased parts or components are to ADC's medical devices and the supplier's performance during supplier evaluations discussed in the sections below.

4.4.2 Executive Management has established a documented sampling plan to ensure that inspected items are randomly sampled during the inspection process. This sampling plan is based upon supplier performance and item or component impact on product realization or the final product.

4.4.3 Executive Management has established a supplier survey and evaluation system to ensure that supplier quality is monitored and measured. This system includes documented procedures for supplier selection, evaluation, and re-evaluation based on the effect the supplier's products have on subsequent ADC devices and the risk posed by the supplier's products to medical devices manufactured by ADC. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained as part of this system.

4.4.4 The supplier evaluation system includes processes for revalidation of existing suppliers at regular intervals to ensure continued compliance with supplier agreements and product requirements. Inputs to the revalidation process include information obtained from monitoring and measurement of supplied product as well as observations related to supplier performance over the evaluation period.

4.4.5 Additional information relating to supplier selection, evaluation, and recordkeeping can be found in SOP 7.0, *Product Realization*.

4.4.6 Executive Management has established the Purchasing Department to purchase items and components used in ADC products. The Purchasing Department ensures that all relevant purchasing information is described in the documentation supplied to the vendor. This information includes:

- Product identification, including quantity and price
- Requirements for product approval
- Requirements for the approval of a vendor's procedures, processes, and/or equipment
- Training requirements applicable to product related processes
- Quality Management System requirements if applicable
- Traceability requirements necessary for the purchased product or components (where applicable)

4.4.7 Purchase requirements are verified by the Purchasing Department prior to their communication to ADC's vendors. In instances where ADC will perform verification of purchased products at a vendor's premises, the details of this verification will be included in the purchasing information supplied to the vendor. Records of this type of verification are maintained as part of ADC's Quality Records.

4.4.8 In cases where a supplier is providing printed materials or other artwork, revisions to the artwork are communicated to suppliers through the use of a revision numbering system to ensure the appropriate artwork is ordered and received by ADC.

4.4.9 It is the expectation that ADC's suppliers will not make alterations or design changes to ordered product without specific, written notifications before-hand to allow ADC to approve all changes. Where appropriate, ADC will maintain written agreements with suppliers to ensure that changes are communicated in a timely fashion. In cases where suppliers are not sophisticated enough to allow for written agreements to exist, strict adherence to inspection protocol will ensure that product changes are detected and reviewed prior to their acceptance.

4.4.10 ADC's Quality Management System incorporates a non-conforming materials reporting system that allows for non-conforming materials to be identified and for decisions to be made regarding their disposition. This includes non-conforming product where the supplier has made alterations to the product design.

4.4.11 As part of ADC's Quality Management System, arrangements have been made to inspect product at select supplier locations in addition to normal inspections performed within ADC's facility to further enhance product quality.

4.4.12 Additional procedures and processes related to ADC's Purchasing Department and product verification activities can be found in SOP 7.0, *Product Realization*. This standard operating procedure includes requirements for records retention for purchasing activities.

4.5 Production and Service Provision

4.5.1 Executive Management has established the processes and procedures necessary to plan and carry out production and service processes under controlled conditions. These processes and procedures are interrelated, as described in the basic ADC process flowchart presented in this Quality Manual. Controlled conditions may include, but are not limited to, the following (as applicable):

- The availability of information that describes the characteristics of the product, including relevant documentation required by national or international regulations (such as Device Master Records or Technical Files)
- The availability of work instructions to the employees that require them, including reference materials and/or measurement standards
- The requirements for equipment or other utilities where that equipment could affect the performance or safety of the product or the safety of ADC personnel
- The availability and use of monitoring and measuring devices, particularly for the testing and/or verification of medical devices that have a measurement function (including device calibration as appropriate)
- The implementation of monitoring and measurement, including the inspection of incoming materials, in process products, and finished products
- The implementation of release, delivery, and post-delivery activities
- Labeling and packaging requirements and any special environmental controls or employee training necessary to ensure product conformity

4.5.2 Executive Management has established the necessary processes to record traceability information related to ADC products on the market to ensure that safety or performance issues can be appropriately addressed. These records include production history and inspection status information and are verified at the time of their creation.

4.5.3 Additional information relating to the control of production and service provision can be found in SOP 7.0, *Product Realization,* and is documented in various work instructions and procedures that make up ADC's Quality Management System.

4.6 Cleanliness of Product and Contamination Control

4.6.1 Executive Management has established environmental controls to ensure that the cleanliness of ADC products is maintained throughout the manufacturing and storage processes. These controls ensure that products with special cleanliness requirements are handled appropriately to avoid contamination of new or existing products.

4.6.2 As part of the process of introducing a new product, the cleanliness requirements for products will be evaluated prior to any production of these products. Where new environmental controls are needed, Executive Management will ensure that these controls are in place before any products are produced. These controls may include environmental controls for sterility of products if applicable to a new product, although ADC currently does not produce sterile products.

4.6.3 Additional information relating to product cleanliness and contamination control may be found in SOP 6.0, *Resource Management,* and in various work instructions and procedures that make up ADC's Quality Management System.

4.7 Installation Activities

4.7.1 ADC does not currently produce products that require special installation processes. As part of the process of introducing new product, these products will be evaluated in order to determine whether or not installation will be necessary for the end-user.

4.7.2 Should it be determined that a new product produced by ADC will require additional installation processes, these processes will be clearly documented, including acceptance criteria as well as verification activities to ensure that the installation of the medical device was completed correctly.

4.7.3 Records of any installation processes will be maintained as Quality Records by ADC and will be documented in specific work instructions should products that require installation be manufactured or offered by ADC.

4.8 Servicing Activities

4.8.1 Executive Management has established the Service Department to ensure that ADC products are properly serviced and maintained. These servicing activities occur on ADC's premises only, and at this time do not include any repairs or maintenance at customer owned facilities. The Service procedures are outlined in QMS work instructions and include proper disposal of environmentally sensitive components.

4.8.2 As part of ADC's service process, service data is analyzed regularly and all repairs and credits are evaluated to determine if they constitute a complaint. Service record analysis allows for an evaluation of ADC products to make determinations related to product improvement.

4.8.3 The Service Department has a number of established procedures and work instructions to ensure that ADC products are repaired to acceptable levels of performance and safety. Additional information relating to these procedures may be found in SOP 7.0, *Product Realization.*

4.8.4 Records of repair/maintenance work performed by the Service Department are maintained as Quality Records.

4.9 Particular Requirements for Sterile Medical Devices

4.9.1 At this time, ADC does not produce sterile medical devices. Should a product be developed that requires sterilization by ADC, the requirements for sterility will be clearly documented, with process parameters clearly defined and sterilization records maintained that are traceable to each batch of product produced. Verification and validation of these sterilization processes would be included in the documented procedures and work instructions.

4.10 Validation of Processes for Product and Service Provision

4.10.1 Although most processes performed by ADC to manufacture finished products can be verified by subsequent monitoring or measurement, any process that is established for production purposes that cannot be verified will be validated prior to its acceptance as a standard manufacturing process.

4.10.2 This validation is performed for processes where deficiencies become apparent only after the product is in use or a service has been delivered. This validation will demonstrate the ability of the processes to consistently achieve their state objectives and parameters. Records of any validation will be maintained as part of ADC's Quality Management System.

4.10.3 Where production and service processes do not have easily verifiable outputs, process validation will occur and be recorded in stand-alone work instructions or standard operating procedures using the following points as reference:

- Process validation requires specific criteria in order to achieve planned results, and ADC's validation plans include the specifics of the review and approval of the process.

- If the validation process requires specialized equipment or specific training prior to implementation, this will be outlined in the QMS documents generated for the process.
- The specific procedure used to perform the validation is documented to ensure consistency during validation and revalidation of the process. (Note: this includes acceptance criteria where inspection and testing are involved.)
- Where sample sizes are being used on representative product, a description of the sampling plans and statistical rationale used to develop the validation process must be recorded.
- The type of records that will be generated and retained for the process validation is determined.
- If it is anticipated that the validated process will require revalidation for any reason (i.e.: shifting machinery, maintenance, part swaps, etc.), the criteria and timeframes for revalidation are determined.
- In some instances, validated processes may be changed or updated, and the criteria used to approve changes to previously validated process is outlined in that process work instruction, or in a stand-alone work instruction as appropriate.

4.10.4 Processes that make use of computer software that could affect the ability of ADC's products and services to conform to requirements, this software will also be validated prior to its use. Software validation requirements will be based on the risks associated with the software in question and its application within ADC's QMS.

4.10.5 While ADC does not currently manufacture or produce sterile medical devices, should such products be introduced in the future it will necessitate the inclusion of sterility process validation. Such processes would be documented and validated in accordance with this Quality Manual and the referenced Standard Operating Procedures.

4.10.6 Process validation and the records required for this activity are discussed in further detail in SOP 7.0, *Product Realization.*

4.11 Identification and Traceability

4.11.1 Executive Management has established an item numbering system to ensure that products, sub-assemblies, and component parts are easily identified throughout the product realization process.

4.11.2 Executive Management has established inspection status procedures to ensure that products are identified with respect to monitoring and measurement requirements. This includes all aspects of the inspection process, from received goods to finished products. These procedures ensure that only products that have passed through specific monitoring and measurement processes are provided to the customer.

4.11.3 Executive Management has established a lot numbering system to ensure product traceability. While traceability is not a requirement for any of ADC's existing products, it allows ADC to easily recall potentially non-conforming products from the market. This lot numbering information is recorded and maintained as part of ADC's Quality Records.

4.11.4 Executive Management has established service and repair processes to ensure that returned items are clearly identifiable and are not confused with conforming product. Additional processes also ensure that non-conforming components and other materials are not used in manufacturing processes.

4.11.5 ADC currently does not produce active implantable medical devices or implantable medical devices with additional record keeping requirements. Should such products be introduced at a future date, records of the distribution of such products will be retained. In addition, ADC would create policies to ensure that ADC's distribution chain maintains such records to connect the tracked devices directly to the end user. These processes would be documented in stand-alone work instructions for the specific product.

4.11.6 In addition to lot numbering, ADC's Quality Management System incorporates a system for Unique Device Identification such that all ADC products are assigned a unique identifier.

4.11.7 ADC's Quality Management System includes procedures for ensuring that devices returned for repair, credit, or servicing are segregated from raw materials and finished medical devices.

4.11.8 ADC's Quality Management System includes procedures for capturing device distribution information to allow for monitoring of product in the field and the issue of field safety notices or product recalls where necessary.

4.11.9 Additional information about product identification and traceability is available in SOP 7.0, *Product Realization,* and is also documented in various procedures and work instructions that make up ADC's Quality Management System.

4.12 Customer Property

4.12.1 Care will be exercised with Customer property while it is under ADC's control or being used by ADC. Customer property for use or incorporation into finished products will be identified, verified, protected, and safeguarded.

4.12.2 Any Customer property that is lost, damaged, or otherwise found to be unsuitable for use will be reported to the Customer and records shall be created to document such issues. Refer to SOP 7.0, *Product Realization* for additional information about procedures dealing with customer property.

4.12.3 It is important to note that "customer property" can be interpreted to mean intellectual property or confidential health information as well as physical property.

4.13 Preservation of Product

4.13.1 All products and components will be preserved throughout the manufacturing, storage, and handling processes to ensure product conformity with specifications. These preservation processes will be in effect up to and including the time of delivery to the intended destination.

4.13.2 Preservation of product includes all procedures and work instructions necessary to describe the identification, handling packaging, storage, and protection requirements for ADC products. Where applicable, these processes also include environmental controls to ensure that factors in the environment do not degrade the quality of ADC products or components.

4.13.3 Executive Management has established processes to ensure that products with limited shelf lives or components with limited shelf lives are monitored to ensure that expired products or components are not used in manufacturing processes.

4.13.4 Product packaging is considered as part of the preservation process to ensure that the product packaging is designed to protect the product during storage, shipment, and handling and maintain the performance and quality specifications of the devices manufactured under ADC's QMS. This is accomplished through ADC's product review during Product Meetings.

4.13.5 Additional information relating to preservation processes can be found in SOP 7.0, *Product Realization*, and is also available in various work instructions and procedures that make up ADC's Quality Management System.

4.14 Control of Monitoring and Measuring Devices

4.14.1 Executive Management has established the necessary monitoring and measurement processes needed to ensure that products and components conform to specified requirements. These processes include detailed instructions for the use of test equipment to verify product conformity and, where necessary, verification of the environmental conditions necessary to perform testing. These processes ensure that monitoring and measurement activities can and are carried out to meet all stated requirements.

4.14.2 As part of the processes established to control measuring equipment, this equipment is calibrated or verified at specific intervals against measurement standards traceable to the National Institute of Standards and Technology (NIST). Procedures have been created to ensure that all equipment is within calibration prior to use. Where no standards exist to indicate the calibration requirements for measuring equipment, the basis used for calibration or verification is recorded in various work instructions or procedures.

4.14.3 Measuring equipment will be adjusted or re-adjusted as necessary to ensure that it is within acceptable calibration prior to use. In addition, all equipment will be identified to enable the calibration status to be determined, safeguarded from adjustments that would invalidate the measurement result, and protected from damage and deterioration during handling, maintenance, and storage.

4.14.4 Executive Management has established procedures and processes to ensure that measurement results that were based on non-conforming (out of calibration) equipment are assessed and the validity of these results are recorded to ensure that product quality and customer safety has not deteriorated as a result of the non-conforming equipment. This system includes the process of correcting non-conforming product and ensuring customer satisfaction.

4.14.5 As part of the processes used to control monitoring and measurement equipment, Executive Management has established a calibration database and calibration records to ensure that all calibrated and controlled equipment is recorded, and the results of calibration and/or verification are maintained as Quality Records.

4.14.6 Included within ADC's process for controlling monitoring and measurement equipment is any computer software used for these purposes. This software would require verification in the same fashion as physical equipment.

4.14.7 Additional information about ADC's monitoring and measurement equipment can be found in SOP 7.0, *Product Realization,* and in various work instructions and procedures that make up ADC's Quality Management System.

Section 5: Measurement, Analysis, and Improvement

5.1 General

5.1.1 Executive Management plans and implements the monitoring, measurement, analysis, and improvement of processes needed to demonstrate product conformity, ensure conformity of the Quality Management System, and to maintain the effectiveness of the Quality Management System.

5.1.2 A variety of procedures and processes have been established to document this improvement and maintenance process. The creation of these procedures and processes include statistical techniques necessary to maintain and improve the Quality Management System where applicable to ADC's procedures and processes.

5.1.3 Refer to SOP 8.0, *Measurement, Analysis, and Improvement,* for additional information relating to these processes.

5.2 Monitoring and Measurement

5.2.1 As part of ADC's Quality Management System, several systems have been established by Executive Management to ensure that product and customer related information from the field is recorded, reviewed, and acted upon.

5.2.2 An electronic Complaint System has been established to monitor customer feedback and to record customer complaints. This system has been designed to ensure that all customer complaints are investigated in a timely fashion and that the results of this investigation are recorded as part of ADC's Quality Records.

5.2.3 ADC's Complaint System includes processes for creating and maintaining customer complaint records, evaluating customer feedback to determine if it meets the definition of a complaint, and complaint investigations. The Complaint System is linked to ADC's vigilance procedures to ensure that regulatory reporting requirements are understood and met, as well as the corrective and preventive action system.

5.2.4 ADC's complaint system is tied to the service procedures established within the Quality Management System to ensure proper handling of customer property and items related to complaints and complaint investigations. Where an investigation will not be performed, records of the justification for not investigating the complaint are recorded.

5.2.5 This system also ensures communication between ADC and our suppliers where investigations yield evidence that supplier actions may have contributed to a complaint, and communication with external end points where user actions or other factors may have contributed to a complaint.

5.2.6 In addition to this complaint system, processes have been established that allow ADC to monitor customer feedback and customer satisfaction levels. This feedback is analyzed by Executive Management to allow ADC to improve its Quality Management System.

5.2.7 Executive Management has direct overview of both the Complaint System and the feedback processes. This allows any quality issues or potential safety problems to be addressed in a timely fashion through ADC's corrective/preventive action and risk management systems and enable ADC to modify existing parts of the QMS to respond to trends found in the field related to our products or services.

5.2.8 ADC's Quality Management System will make use of experience gained from post-production feedback to ensure that our products continue to meet all requirements, and to ensure that our level of service continues to satisfy our customers. This data is analyzed regularly through various internal reports collected within the Quality Management System.

5.2.9 Where complaints are identified by ADC's vigilance system as requiring regulatory reporting, advisory notices, or other actions, the Quality Management System includes specific procedures and processes documenting how these actions are undertaken to ensure regulatory compliance.

5.2.10 Additional information relating to ADC's monitoring and measurement system can be found in SOP 8.0, *Measurement, Analysis, and Improvement,* and in various work instructions and procedures that make up ADC's Quality Management System.

5.3 Internal Auditing

5.3.1 Executive Management has established an internal auditing process to audit the Quality Management System. This auditing process ensures that the Quality Management System has been effectively implemented and is maintained. Through continuous monitoring of internal processes, the auditing process will also:

- Ensure that ADC is compliant with the national and international regulations indicated earlier in this manual.
- Ensure that ADC is compliant with established procedures and processes included within the Quality Management System.
- Ensure that skills, training, and/or departmental performance does not degrade by re-auditing departments on a pre-scheduled basis

5.3.2 As part of ADC's internal auditing process, audits will be conducted for every department within the company. As each audit is planned the importance of the processes being reviewed will be evaluated to ensure that audits are conducted appropriately. Auditors will be selected to ensure that all audits are conducted in an impartial fashion, and so that auditors will not audit their own work.

5.3.3 ADC's auditing process includes work instructions and procedures that define audit frequency, scope, and auditing methods. This documentation also defines the responsibilities of planning and conducting audits, as well as the reporting requirements.

5.3.4 Departments that have non-conformities detected during the internal auditing process will correct those non-conformities in accordance with ADC's established corrective/preventive action system. These non-conformities will be corrected in a timely manner (including the underlying cause of the non-conformity). Follow-up audits and/or inspections as required by corrective/preventive actions will verify that corrections have been made and that they are effective in eliminating the detected non-conformities.

5.3.5 Additional information pertaining to ADC's internal auditing processes can be found in SOP 8.0, *Measurement, Analysis, and Improvement*

5.4 Monitoring and Measurement of Processes

5.4.1 Executive Management has established various monitoring and measurement techniques to ensure that the processes associated with the Quality Management System are monitored. This ensures that processes can achieve planned results.

5.4.2 Data is collected throughout ADC's various departments for regular analysis as well as long term analysis through mechanisms such as ADC's Management Review process.

5.4.3 With the use of data collected during the monitoring and measurement of processes, all departments are aware of their status in terms of quality and the achievement of planned objectives. Issues that are discovered during this review of process data allows corrective and preventive actions to be taken to ensure that there is no adverse impact on product conformity.

5.4.4 Additional information pertaining to ADC's monitoring and measurement processes can be found in SOP 8.0, *Measurement, Analysis, and Improvement.*

5.5 Monitoring and Measurement of Product

5.5.1 Products manufactured by ADC are monitored and measured to ensure that all products conform to documented specifications. As determined by Executive Management, this monitoring and measurement is performed at three stages of product realization; incoming inspections, in-process inspections, and finished product inspections.

5.5.2 All monitoring and measurement processes result in Quality Records that provide evidence of product conformity to acceptance criteria. These records indicate the date of the inspections and the person(s) authorizing the release of finished product as applicable. The requirements for these records are included in individual work instructions that detail specific inspections performed throughout ADC's Quality Management System.

5.5.3 Products are not released and shipped to customers until these inspections have been completed and all products have been determined to comply with the stated requirements. Where products have been produced that do not meet all the requirements that were originally stated, these products will only be authorized for release by Executive Management and, where appropriate, by the customer. (Note: the concept of releasing "products that do not meet stated requirements" is taken to mean products that have cosmetic defects only; it doesn't refer to non-conforming product that could affect the health or safety of the end-user or patient.)

5.5.4 At this time, ADC does not currently manufacture implantable or active implantable medical devices that would require additional record keeping during the inspection/testing activities prior to product release. Even without the production of these products, as part of the record keeping processes that make up ADC's Quality Management System, the identity of the personnel performing inspection and testing activities is recorded during IQC and FQC inspections.

5.5.5 Additional information relating to ADC's inspection and testing processes can be found in SOP 8.0, *Measurement, Analysis, and Improvement*, and in various work instructions and procedures that make up ADC's Quality Management System.

5.6 Control of Nonconforming Product

5.6.1 Executive Management has established documented procedures and work instructions to control the disposition, retention, and marking of product that does not conform to requirements. This system is designed to ensure that non-conforming products or components are properly identified, segregated, and not used in finished products or delivered to customers.

5.6.2 The departments responsible for handling non-conforming products or components, as well as the controls used to identify these materials and to quarantine them, are included in various work instructions and procedures that make up ADC's Quality Management System. Included within these procedures are the requirements for documentation of non-conformities and the actions taken in relation to these products or components.

5.6.3 ADC's non-conforming materials report system has been created to document evaluations of non-conformities, the need for an investigation, and actions taken both to correct the non-conformity and to contact the parties responsible for them such as the suppliers.

5.6.4 Nonconforming product is dealt with in one or more of the following ways:

- By acting to eliminate the detected nonconformity, either through the re-work of affected materials or the replacement of affected components/products
- By authorizing its use, release, or acceptance under concession by Executive Management and, where applicable, by the Customer
- By acting to preclude its original intended use or application through reject marking procedures and quarantine of affected stock

5.6.5 Due to the fact that ADC products are medical devices, non-conforming product will be accepted for use through concession only after it has been determined that all applicable regulatory requirements for the product have been met. (In other words, while a non-conforming product with a cosmetic defect might be accepted for use through concession, a non-conforming product that did not meet applicable safety requirements would not.)

5.6.6 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained as part of ADC's Quality Management System. These records include the identity of any personnel authorizing the use of non-conforming product (with the customer's concession where appropriate).

5.6.7 As part of ADC's system for handling non-conforming materials, any materials that are re-worked to make them conform to ADC requirements will be subjected to re-inspection to ensure that the re-work has succeeded in correcting the detected non-conformities. Reworks are only performed once the potential adverse impacts of the rework process have been considered and the process is documented and approved through a standard approval process. NCMR and/or CAPA files will also be used to further detail information pertaining to reworks under the procedures outlined in ADC's QMS.

5.6.8 ADC's Complaint System, as well as customer feedback and information obtained from the Service Department are used to help detect any potential non-conforming product in the field. When nonconforming product is detected after delivery or use has started, appropriate actions to the effects, or potential effects, of the nonconformity will be taken through ADC's corrective/preventive action system. These actions will be documented and records will be included as Quality Records.

5.6.9 ADC's complaint and vigilance systems include processes for creating advisory notices or recall notifications where it has been determined that non-conforming product must be withdrawn from the field or corrected prior to use.

5.6.10 Additional information relating to the control of nonconforming product may be found in SOP 8.0, *Measurement, Analysis, and Improvement*, and in various work instructions and procedures that make up ADC's Quality Management System.

5.7 Analysis of Data

5.7.1 As part of the Quality Management System, Executive Management has established processes for the collection and analysis of quality related data. Analysis includes the use of appropriate statistical techniques where applicable. (Note: this data also includes relevant customer satisfaction information.)

5.7.2 The data collected is used to determine the suitability and effectiveness of ADC's Quality Management System and to note areas where improvement can be made. This data is reviewed by Executive Management and specified department supervisors to ensure that trends and quality issues detected during analysis is properly communicated and addressed. This data is presented in several different forums, including, but not limited to:

- Regularly scheduled Management Review Meetings
- Plant Manager Meetings (including plant departmental supervisors)
- Product Meetings (focusing on new product development or existing product issues)

5.7.3 The data analyzed as part of ADC's Quality Management System includes, but is not limited to:

- Customer satisfaction (including customer feedback and complaints)
- Conformity to product requirements (including data obtained through repair and service processes as well as non-conformities)
- Characteristics and trends of processes and products, including opportunities for preventive action (Note: process analysis includes all aspects of ADC's product realization cycle as well as after-market services. Preventive action may refer to opportunities for improvement as well as problem prevention.)
- Supplier evaluations
- Internal and external audit data

5.7.4 ADC's preventive and corrective action systems, discussed further in this manual, are used to address problems or opportunities identified through analysis of data.

5.7.5 Analysis of data is performed in accordance with SOP 8.0, *Measurement, Analysis, and Improvement*. Additional information relating to this process can also be found in various procedures and work instructions that make up ADC's Quality Management System.

5.8 Improvement

5.8.1 The purpose of ADC's Quality Management System, beyond the basic concept of product quality and customer satisfaction, is to ensure that ADC continues to grow as an organization and improve its operations to increase efficiency, to increase product quality and to increase customer satisfaction levels.

5.8.2 ADC's Quality Management System incorporates various tools that help make this continual improvement effort possible. Some of these tools are detailed below:

- ADC's Quality Policy has been designed to outline the basic quality goals that the company hopes to achieve
- ADC's Quality Objectives outline more specific improvement objectives, and are reviewed by Executive Management to ensure that they are suitable for the company and to gauge their effectiveness
- ADC's internal quality auditing system ensures that departments are performing processes as determined by written work instructions and other documents, areas of concern are noted and corrected
- Data analysis allows for trending of potential quality issues and customer satisfaction levels
- ADC's corrective/preventive action systems allow issues to be averted before a quality issue develops, take advantage of opportunities, or to correct existing problems and improve efficiency
- The Management Review process allows Executive Management to review the whole Quality Management System and make improvements where appropriate.

5.8.3 As part of ADC's commitment to quality, a system has been implemented to allow ADC to issue advisory notices or recalls on ADC products that have been supplied to our customers. This system can be implemented whenever necessary to ensure that customers are aware of any urgent quality issues that relate to ADC products. This system is further supplemented by ADC's Customer Service and Quality Assurance Departments, which provide customers with up-to-date, accurate technical and/or regulatory information as necessary.

5.8.4 ADC's continual improvement initiative includes a Complaint System. This system is designed to record the details of all customer complaints, and allows for this information to be routed to the departments responsible for the complaint so that investigation may be performed. All complaints are investigated and reviewed so that the customer's satisfaction is guaranteed, and the actions taken to resolve the complaint (and underlying issues relating to the complaint where appropriate) will be documented so that they can be easily reviewed.

5.8.5 Where investigation indicates that a customer complaint may have been caused by activities that are outside of ADC's direct control, ADC's advisory notice system ensures that this information is shared with all relevant parties, allowing for the resolution of any quality issues.

5.8.6 ADC's Quality Management System includes a process for notifying relevant regulatory authorities when adverse events occur that involve ADC devices. The criteria for reporting these events and the method of reporting are included in documented work instructions and procedures as referenced previously in this manual.

5.9 Corrective Action

5.9.1 Executive Management has established a corrective action system to ensure that corrective actions are issued and implemented to effectively handle customer complaints, product non-conformities, and process non-conformity. The system involves the investigation of the causes of non-conformity, recording the results if the investigation determines action(s) must be taken to alleviate the problems, and devising methods for ensuring corrective action(s) are effective. (It is important to note that ADC's Complaint System is a stand-alone system specifically for dealing with customer complaints and may feed into the corrective action system directly.)

5.9.2 ADC's corrective action system includes processes for reviewing nonconformities and determining their cause. Once this determination has been made, actions to correct the nonconformity can be developed. Actions are also developed to prevent a recurrence of the nonconformity in the future. These actions are then implemented, and are available to Executive Management for review at any time.

5.9.3 As part of the implementation of corrective actions, it may be necessary to update existing Quality Management System documentation to prevent future recurrences of the detected non-conformity. Updates to existing documentation that are required during corrective actions are performed in the same fashion as regular document revisions.

5.9.4 Corrective action files will contain records detailing the entire corrective action process, from the identification of the problem and root cause analysis to the details of the actions taken to correct the problem including the results of any investigations performed. These records allow for the review of the corrective action files before they are closed to ensure that they have been effective.

5.9.5 As part of the corrective action system, the risks posed by the detected non-conformities and the risks associated with any planned corrective actions are evaluated prior to the implementation of corrective action plans.

5.9.6 Additional information relating to the corrective action system can be found in SOP 8.0, *Measurement, Analysis, and Improvement*, and in various work instructions and procedures that make up ADC's Quality Management System.

5.10 Preventive Action

5.10.1 Executive Management has established a preventive action system to ensure that preventive actions will be issued and implemented to detect, analyze, and eliminate potential causes of problems or to take advantage of opportunities. Actions will include the steps to implement preventive actions, methods to ensure implemented actions are effective, and procedures to maintain records of all preventive actions for Management Review.

5.10.2 As with the corrective action system, the preventive action system will involve the creation of preventive action files that contain all relevant information about specific preventive actions. These files will include the initial potential problem, root cause analysis, and investigation results, and will allow a review of the preventive action file before it is closed to ensure that the preventive action has been effective.

5.10.3 The preventive action system includes processes for:

- Determining potential nonconformities and their causes
- Identifying potential opportunities and their benefits
- Evaluating the need for action to prevent occurrence of nonconformities or to take advantage of opportunities
- Determining and implementing action needed
- Recording the results of action taken
- Reviewing preventive action taken

5.10.4 In a similar fashion to the corrective action system, the risks associated with preventive actions are evaluated prior to implementation of any preventive action plans. Actions are evaluated to ensure that they will not have an adverse impact on ADC's Quality Management System, internal processes, or product performance/safety.

5.10.5 Additional information relating to the preventive action system can be found in SOP 8.0, *Measurement, Analysis, and Improvement*, and in various work instructions and procedures that make up ADC's Quality Management System.

Revision Control Table				
Rev #:	Rev Date:	Revision History Filename:	Creator:	Approver:
11	12/19/19	*Quality Manual,* Rev 10 to 11	M. Falco	K. Silk
12	5/20/2020	*Quality Manual,* Rev 11 to 12	M. Falco	K. Silk