GM Nameplate

Washington Division

Quality Management Systems Manual

ISO 13485:2003

ISO 13485 Quality Management Systems (QM) Manual

This manual describes the quality management systems structure at GM Nameplate which has been implemented to meet the ISO 13485:2003 Quality Management Systems and FDA 21 CFR parts 820 criteria. For quality management system conformation to differing requirements of ISO 9001 and AS9100 see GM Nameplate Quality Manual 00-QM-01 under different cover.

Revision History

Revision	***Date***	***Description of change***
00	5/28/13	New-creation of quality manual
01	10/15/13	2587-Change QM number to 01-QM-MED, clarify distinction between the 2 quality manuals, update exclusions to include 7.3.7, other minor clarifications

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This document will be in effect as of the date that the last signature is obtained on this document. This manual is a controlled document and revisions to this document will follow the process for revising a controlled document at GM Nameplate.

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Approval Signatures:

10-15-13

GM Nameplate CEO – Bruce Cleckley **Date**

10-15-13

Corp. Director of Quality – Martin Espinola **Date**

10-16-13

Washington Division President – Brad Root **Date**

10-15-2013

Washington Div. Quality Director – Michael Wodrich **Date**

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MISSION STATEMENT

We are committed to the prosperity of our customers, fellow employees, our community, and our company; we must build strong partnerships with all of them.

Using our Quality Management System as a tool, GM Nameplate's management promotes ethical compliance to applicable statutes and regulations.

QUALITY POLICY STATEMENT

"Providing products and services that meet or exceed customer expectations, continually improve in everything we do, and maintain the effectiveness of the quality management system"

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0 INTRODUCTION

0.1 General

GM Nameplate is a global manufacturer that provides custom-engineered solutions to leading medical device companies worldwide. GM Nameplate capabilities include user interface devices, front panel integration, labels, nameplates, safety decals, plastic molding and decorating, quick-turn prototyping, die-cut components, value-added assemblies and more.

GM Nameplate offers contract manufacturing services for touch screens, membrane switches and other switch technologies, biosensors, value-added assemblies to its medical device clients. These products are considered components and are not a finished medical device. GM Nameplate does not manufacture any finished medical device product per medical device description.

GM Nameplate's Quality Management System described by this Quality Manual covers the manufacturing of various components for medical device products at the Seattle, Washington Division.

0.2 Process Approach

This Quality System Manual has been developed to reflect GM Nameplate's quality management system in compliance with ISO 13485:2003, ISO 14971:2007, and FDA's Regulatory requirements.

A system based process approach to quality management at GM Nameplate allows that all activities that receive inputs and convert the inputs to outputs be identified as a process. Processes that are linked to other processes are also identified and managed accordingly.

0.3 Relationship With Other Standards

Although ISO 13485 is a stand-alone standard it is based on ISO 9001:2008. GM Nameplate's ISO 13485 Quality Management Systems Manual is established for the purposes of continuity between the two standards, ISO 9001:2008 and ISO 13485:2003.

0.4 Compatibility With Other Management Systems

This Quality Manual is applicable to other agency requirements while ensuring a basic foundation for GM Nameplate Quality Management System. The Quality Systems at GM Nameplate complies with the United States Food and Drug Administration - Quality System Regulations (QSR)

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1 SCOPE

1.1 General

The Quality Management System described in this manual is intended to meet the requirements of the quality management systems standard ISO 13485:2003. It also addresses FDA's Quality System Regulations for the production of medical devices.

Our policies provide a framework to ensure conformity of the GM Nameplate's quality management system to ISO 13485 requirements and maintain the effectiveness of the quality system.

The requirements of this manual will be communicated to all GM Nameplate's employees in full or in part, depending on scope of employee's responsibilities and impact on the quality system and/or product integrity.

1.2 Application

The Quality Management Systems described in this manual is specific to non-sterile and non-implantable medical devices components. Our products are custom user interface devices, front panel integration, labels, nameplates, safety decals, and decorating, quick-turn prototyping, die-cut components, and assembly of medical device components, for medical device and InVitro diagnostic industries

GM Nameplate manufactures products to customers' design and specifications. Customers are responsible for control of their design and evaluating risks associated with the design of their products. However in order to manufacture customer products, GM Nameplate is required to produce tools and processes. Design of these tools and processes are not considered "Design" in the scope of this quality manual. GM Nameplate, Inc. produces neither sterile products nor active implantable medical devices and has no particular requirements for these types of products. Additionally, GM Nameplate, Inc. neither installs a product nor requires to providing further services for the custom manufactured products. Therefore the following clauses of ISO 13485 do not apply to GM Nameplate quality management system for medical devices:

a) 7.3, "Design and development"

   i. 7.3.1 through 7.3.6 are excluded but section7.3.7 will be used is used as a guidance tool for customer initiated changes to product design and/or specifications. (See section 7.3 of this manual.)

b) 7.5.1.2, “Control of production and service provision – Specific requirements” which includes the following sections:

i. 7.5.1.2.1, “Cleanliness of product and contamination control”

ii. 7.5.1.2.2, “Installation Services”

iii. 7.5.1.2.3, “Servicing activities”

c) 7.5.1.3, “Particular requirements for sterile medical devices”

d) 7.5.2.2, “Particular requirements for sterile medical devices”

e) 7.5.3.2.2, Particular requirements for active implantable medical devices and implantable medical devices”, and

f) 8.2.4.2, “Particular requirement for active implantable medical devices and implantable medical devices

2 NORMATIVE REFERENCES

ISO 9000: 2008: Quality Management Systems-Fundamentals and Vocabulary

Code of Federal Regulations title 21, Part 820, Quality System Regulation (QSR)

3 TERMS AND DEFINITIONS

3.1 *advisory notice*: notice issued by the organization subsequent to delivery of the medical device, to provide supplemental information and/or to advise what action should be taken in

- the use of a medical device
- the modification of a medical device
- the return to the organization that supplied the medical device, or
- the destruction of a medical device

Advisory notice might be issued in order to comply with national and regional regulatory requirements.

3.2 *customer complaint:* written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, safety, or performance of a medical device that has been placed on the market.

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

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, injury or handicap
- investigation, replacement or modification of the anatomy or of a physical process,
- control of conception,
- disinfections of medical devices,
- providing information for medical purposes by means of in Vitro examination of specimens derived from the human body

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

3.5 *components:* substance, piece part, software, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled medical device.

3.6 *contract*: agreed requirements between GM Nameplates and its customers

4 QUALITY MANAGEMENT SYSTEM

4.1 General requirements

GM Nameplate has identified and established a documented quality management system, and applied processes throughout the organization to maintain the effectiveness of the Quality Management System.

The following processes are identified as those processes required supporting the quality management system.

- Management Review
- Product Realization Plan
- Production Process Control
- Corrective and Preventive Actions
- Internal Audits
- Customer Feedback

The control and support of these processes are assured by:

a) Determination of the sequences and interactions of these processes

b) Determination of the criteria and methods to ensure operation and control of the process are effective,

c) Identification and availability of resources and information,

d) Defined monitoring, measuring and analysis,

e) Implementation of actions necessary to achieve the planned results and to maintain the effectiveness of these processes

f) Implementation of the controls for outsourced processes that affect product quality.

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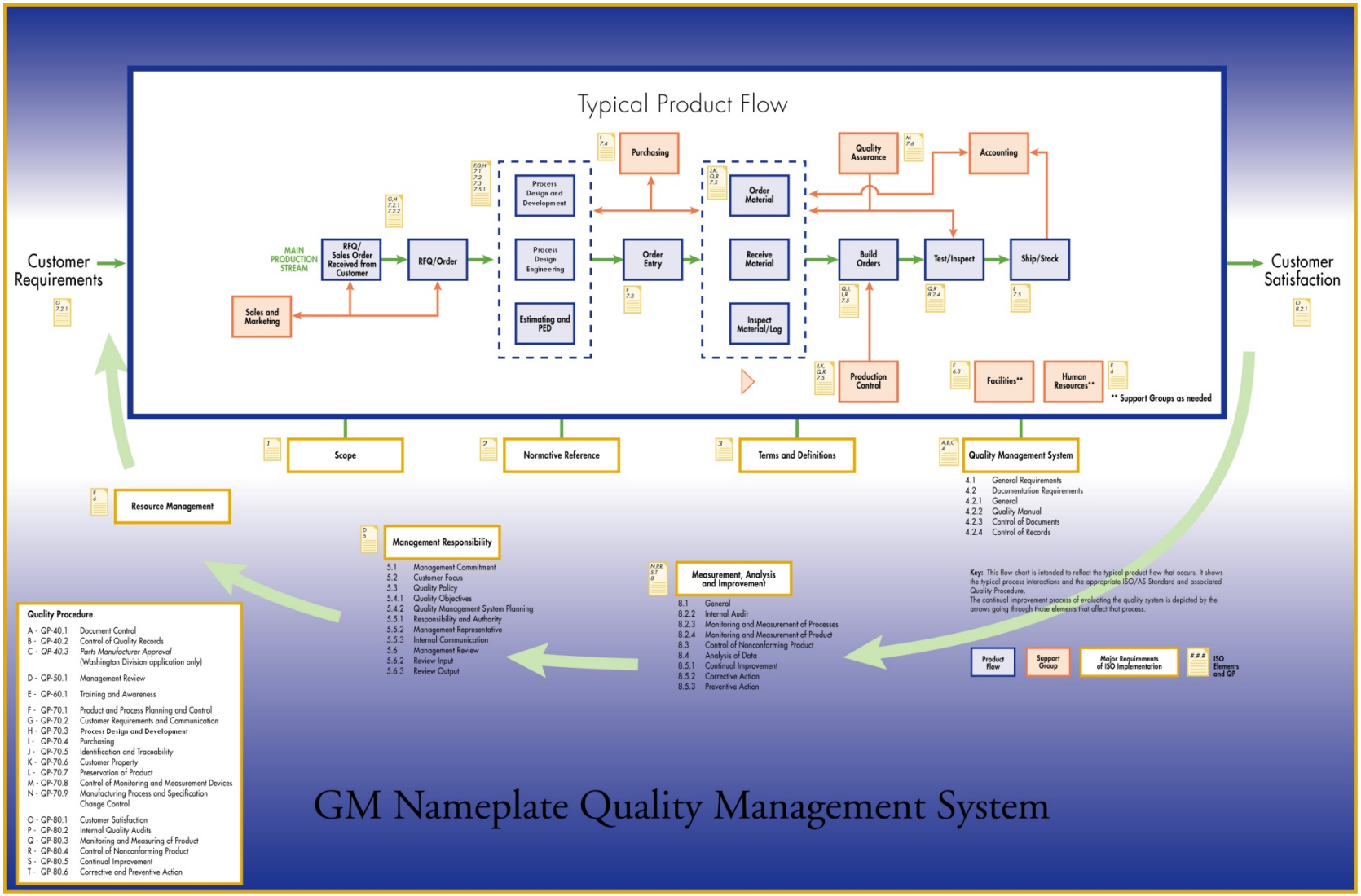

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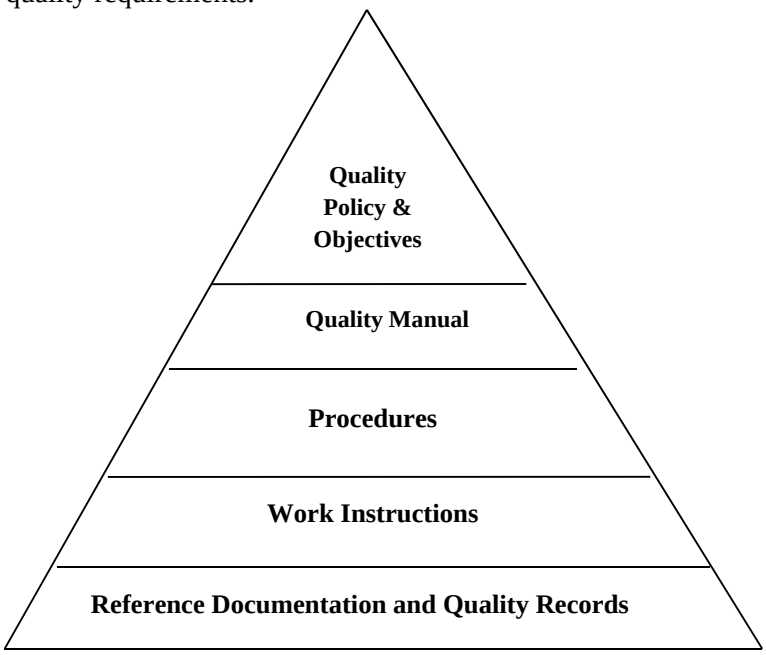
4.2 Documentation Requirements

4.2.1 General

GM Nameplate has established a comprehensive Quality Management System to assure the achievement of its quality policy and objectives. A five level documentation system is used to clearly communicate quality requirements.



Requirements for documentation may originate internally, from the customer, or as they might be required by ISO 13485 and/or FDA regulations.

Management ensures that employees have access and awareness of procedures related to their job responsibilities by providing access to controlled document via computer or binder of controlled paper copies of procedures and required forms.

For each medical device product, GM Nameplates establishes and maintains a Device Master Record file that includes documents defining:

a) product specifications including appropriate customer drawings and specifications,

b) production process specifications, methods and equipment used, and environmental conditions requirements, when required,

c) acceptance criteria for the products provided by the customer,

d) packaging and labeling specifications.

4.2.2 Quality Manual

GM Nameplate has established and maintains a quality manual to define the scope of the Quality Management System requirements and to provide justifications for any exclusion of the standard, ISO 13485 which it is intended to comply.

This Quality manual provides reference to the procedures established for the Quality Management System and also shows the relationship between the procedures and the requirements of the Quality Management Standards.

Level	Document Type	Definition
	Quality Policy and Objectives	The Quality Policy is the statement of our commitment to our customers and is a driving force of our Quality Management System. Quality Objectives are statements of measurable goals to support our Quality Policy.
1	Quality System Manual	This Quality manual provides reference to the procedures established for the Quality Management System also shows the relationship between the procedures and the requirements of the Quality Management Standards.
2	Procedures	Documents used to define in further detail the principles and strategies used to support the elements of the Quality Management System. Procedures are used for groups of people allowing a clear definition of responsibility and interfaces.
3	Work Instructions	Documents that provide the detailed instructions for a single operation. They define what tasks are involved, how they are to be performed, and what reference documentation is needed to perform the task.
4	Reference Documents	Records that need to be consulted in order to follow a procedure or work instruction. The most common reference documentation used at GM Nameplate is the work order ticket (job ticket) which contains the specific requirements for each order, including the part number, materials, specifications, drawings, schedule, stations sequences, ship date and method, etc.
4	Records	Provides evidence of meeting quality requirements and the effectiveness of the Quality Management System.
4	Customers or Regulatory documents	These requirements are documented at divisional level quality management system documentation as applicable to industries and customers served.

GM Nameplate personnel have access to quality management system documentation and are made aware of procedures including changes and revisions needed to carry out their responsibilities.

Customer and regulatory authorities' representatives are also allowed access to GM Nameplate Quality Management System documentation.

4.2.3 Control of Documents

GM Nameplate has established and maintains documented procedures for creation, review and approval, change control, and distribution of all documents and records required by the Quality Management System.

All controlled documents are:

a) Reviewed for adequacy, and approval by authorized personnel before issue,
b) Clearly identify the changes
c) Reviewed for changes to documents and approved prior to use,
d) Written legibly and are readily identifiable,
e) Available at the point of use

Document control at GM Nameplate ensures that all obsolete documents are removed from all points of issue or use promptly and archived in appropriate location.

A master list or equivalent document control procedure are issued by document control to identify the distribution and current revision status of documents.

Documents applicable to control requirements at GM Nameplate that are generated from external origins (industry and international standards, customer specifications, and customer supplied drawing) are also included in the document control system. Documents of external origin are periodically reviewed to assure the most recent versions are in use.

A copy of the obsolete document is retained for a period of time that has been defined in 01-QP-40.2, Control of Quality Records. This period ensures that documents to which medical devices have been manufactured and tested are available as defined by the organization, or as specified by relevant regulatory requirements.

Master file of the original quality records and procedures, forms, and work instructions are maintained by Document Control.

Reference Document: ***01-QP-40.1*** ***Document Control***
01-QP-40.2 ***Control of Quality Records***

4.2.4 Control of Records

GM Nameplate maintains and controls records to provide evidence of conformance to requirements and evidence of the effective operation of our quality management system. Documented procedures have been established to ensure that records are legible, readily identifiable, and retrievable. Controls are defined for the identification, storage, protection, retrieval, and disposition of records.

Records are retained for a minimum of 3 years, or as otherwise specified by customer contract or regulatory requirements.

When forms are used as quality records, the forms shall be identified with a title, form number, revision date and/or number when applicable, or be pictured within a procedure or work instruction.

Reference Document: 01-QP-40.2 Control of Quality Records

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

GM Nameplate executive management is committed to the development, implementation, and maintaining the effectiveness of the quality management systems by:

a) Communicating to all members of the organization the importance of meeting customer, statutory and regulatory requirements,

b) Establishing the quality policy and objectives,

c) Ensuring that quality objectives are established,

d) Conducting periodic management reviews of the Quality Management System,

e) Ensuring that the necessary resources are available.

5.2 Customer Focus

Executive management ensures that customer requirements are determined and met with the goal of increasing customer satisfaction. Customer requirements are determined and satisfaction is measured through our product realization and measurement, analysis and improvement processes and procedures.

Executive management shall ensure that product conformity and on-time delivery are measured and that appropriate actions are taken if planned results are not or will not be, achieved.

5.3 Quality Policy

Our quality policy expresses our commitment to meet or exceed customer requirements and expectations by maintaining the effectiveness of our quality system. The policy establishes a framework by which we establish and review quality objectives, and is periodically reviewed by executive management to ensure its continuing suitability. Executive management ensures that the policy is communicated and understood throughout the organization.

5.4 Planning

Executive management ensures that quality objectives are established and that the Quality Management System is planned to ensure that the quality objectives are met.

5.4.1 Quality Objectives

Measurable quality objectives are established at the appropriate functions throughout the organization that are relevant in supporting the quality policy, meeting the requirements for products and processes, improving quality and performance, and maintaining and enhancing customer satisfaction

These objectives, which represent all departments and employees of the company, measure the effectiveness of the quality management systems relative to the quality policy.

5.4.2 Quality Management System Planning

The Quality Management System is planned to define the processes needed to meet the quality objectives and support the quality policy. Quality management systems' changes are evaluated and planned accordingly during management review to ensure that its integrity is maintained.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibilities and Authorities

The CEO delegates the Corporate Director of Quality and Regulatory as Corporate Management Representative for ensuring that the Quality Management System at all divisions satisfies the requirements of the appropriate Quality Management System Standard(s).

The Director of Quality at Washington division is the Management Representative for this site. The Management Representative is responsible to maintain total compliance with the Quality Management System as well as monitoring and control of product quality. The Management Representative reports to the Division President and the Corporate Management Representative.

Each employee of GM Nameplate is responsible for ensuring:

a) Applicable policies and procedures are followed within their work area,

b) Any process creating non-conforming product is stopped until corrective action is taken,

c) Procedures, which are undefined or fail to satisfy customer requirements are identified for corrective action,

d) Principles and methods of continual improvement are regularly applied to processes.

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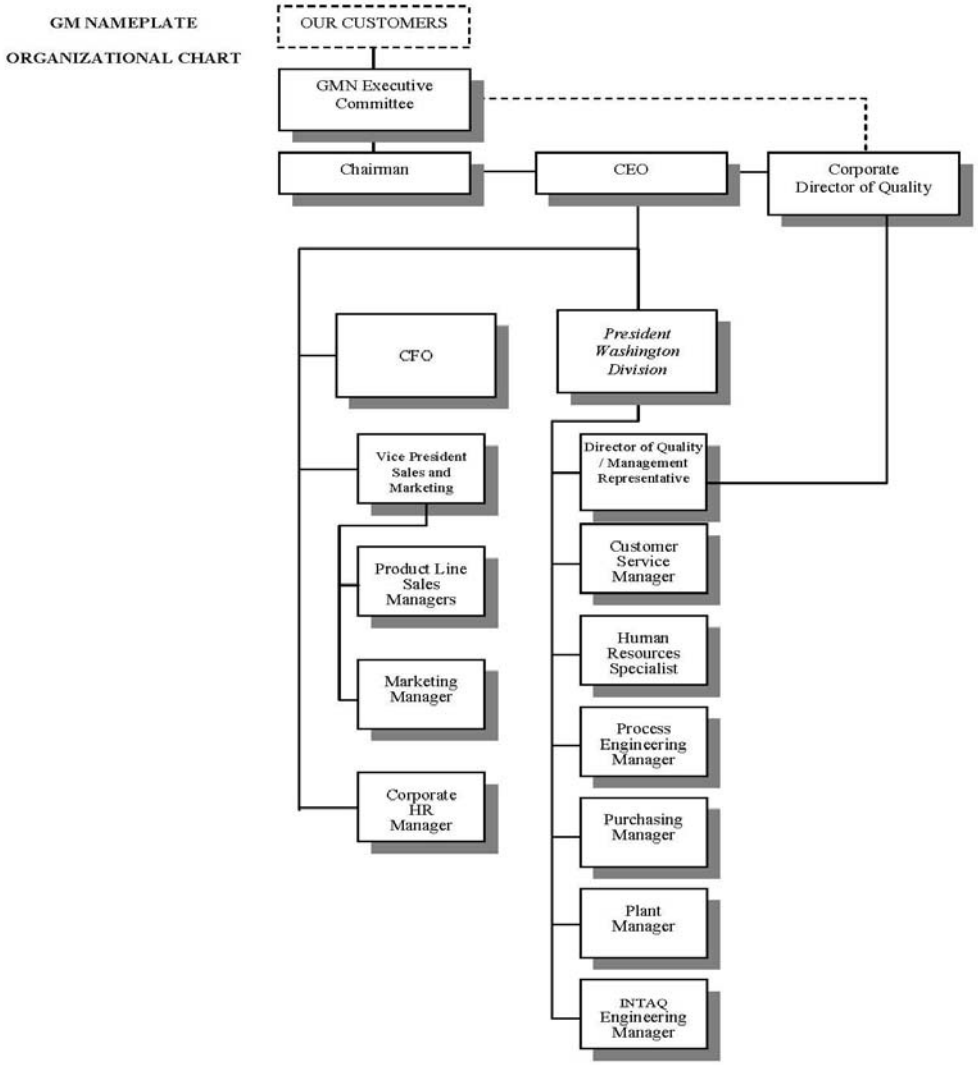

5.5.2 Management Representative

The Director of Quality, Washington division of GM Nameplate serves as management representative and has the responsibility and authority for:

a) Ensuring that the requirements of the GM Nameplate Quality Manual and the processes needed for the quality management system are well defined, implemented and maintained,

b) Reporting on the performance of the Quality Management System to executive management for review and as a basis for improvement of the Quality Management System,

c) Ensuring that awareness of regulatory and customer requirements is promoted throughout the organization.

d) The organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.

Management representative also acts as a liaison with external parties on matters related to the quality management system.

5.5.3 Internal Communication

Executive management ensures that processes for communicating information concerning the Quality Management System are established throughout the organization. Communication includes information regarding:

a) Quality policies,

b) Quality objectives and requirement,

c) Effectiveness of the Quality Management System.

Communication between functions performing specific Quality Management System activities is defined in the documented procedures for those activities. Communication methods also include:

a) Management-led employee meetings,

b) Training sessions,

c) Internal publications, bulletin boards, email.

5.6 Management Review

5.6.1 General

The Quality Management System is reviewed by executive management at planned intervals to ensure it continuing suitability, adequacy, and effectiveness. Additionally management reviews the quality systems to identify the needs for changes or improvements, including the quality policy and quality objectives. Records of these reviews are maintained.

Director of Quality at the Washington Division schedules and maintains records of each Management Review Meeting for the Division.

5.6.2 Review Input

Management review input are include but not limited to information on:

a) results of audits
b) customer feedback
c) process performance and product conformity
d) status of preventive and corrective actions
e) follow-up actions from previous management reviews
f) changes that could affect the quality management system
g) recommendations for improvement, and
h) new or revised regulatory requirements

5.6.3 Review Output

The outputs from the management review are included but not limited to any decisions and actions related to the following:

a) improvement needed to maintain the effectiveness of the quality management system and its process
b) improvement of product related to customer requirements, and
c) resource needs

Reference documents: 01-QP.50.1 Management Review of the Quality Management System

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

GM Nameplate determines and provides the resources to implement and maintain the quality management system; and to maintain the effectiveness and meet regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

All personnel performing work affecting conformity to product requirements are ensured to be competent on the bases of appropriate education, training, skills and experience as needed to successfully fulfill their responsibilities.

6.2.2 Competence, Awareness and Training

GM Nameplate documented procedures requires competence for personnel performing activities affecting product quality and their training requirements.

A training certification process is used to train, certify, and record that employees have been properly trained to documented process and quality procedures within the scope of the Quality Management System.

Training is periodically evaluated to assess its effectiveness in meeting goals and requirements. Methods used to evaluate training effectiveness include internal and external audits, employee performance reviews, and quality and productivity data.

The appropriate records of training, education, skills, and experience are maintained by the Human Resources Department.

6.3 Infrastructure

The infrastructure needed to assure conformance to quality requirements is determined, provided, and maintained. Infrastructure includes, as applicable:

a) Buildings, workspaces and associated utilities,

b) Process equipment (hardware and software),

c) Supporting services (communication, transport, etc.).

6.4 Work Environment

A suitable work environment is provided to ensure that conformity to product requirements are achieved. Work environment requirements are established during product realization planning. Considerations are given to both human and physical factors that can affect product conformity. Factors to be considered include:

a) Safety rules, including the use of protective equipment,

b) Ergonomics,

c) Temperature, humidity, light, air flow, protection from ESD,

d) Cleanliness, pollution, noise, hazardous materials,

e) Compliance will all relevant standards, codes, laws,

f) Methods to enhance employee involvement, motivation, and satisfaction, such as recognition programs.

Reference documents: 01-QP-60.1 Training and Awareness

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

GM Nameplate's customers develop the design and finished device specifications and requirements for acceptance.

GM Nameplate plans and develops the processes needed for product realization through the preparation of Device Master Record, which includes production steps, equipment requirements, and quality requirements consistent with the quality management system.

Product realization planning is controlled and documented through the interdepartmental participation. This process includes defining:

- Resource requirement,
- Product and personnel safety,
- Reliability, availability and maintainability,
- Monitoring/measuring requirements,
- Manufacturability and inspectability,
- Suitability of parts and materials used in the product,
- Developing the processes and equipment, in accordance with customer requirements, customer technical specifications, and Quality Management System requirements,

The primary output of this process is the Device Master Record which includes work order job ticket, which includes the basic manufacturing and quality plan. Output may also include additional work instructions, inspection, and test plans, project plans and control plans.

Risk management activities are documented and records maintained throughout the product realization process. Risk management processes including risk assessment. Products manufactured at GM Nameplate are components to a medical device and there is often limited information available to allow for product risk management activities. Most of the times the intended use of products is not known as the design and specifications for these devices are provided from external sources. However GM Nameplate performs process risk assessment during product realization planning stage to identify risks associated with the production process.

The effectiveness of risk management of GM Nameplate products are monitored through returned materials or complaints processes or activities and subsequent trend analysis of data. Productions are scheduled based on customer orders.

Reference document: 01-QP-70.1 Product and Process Planning and Control

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

GM Nameplate maintains documented procedures to control activities associated with review of customer orders including the requirements for delivery and post-delivery activities.

Requirements related to the product are determined during Request for Quotation (RFQ) and Contract Review processes, involving Sales, Design Engineering, Process Engineering, Quality Engineering, Customer Service and other functions as appropriate. Identified are:

a) Requirements specified by the customer, including delivery and post-delivery requirements,

b) Requirements not specified by the customer but necessary for the specified or intended use of the product,

c) Requirements related to statutory and regulatory requirements,

d) Any additional requirements identified by GM Nameplate.

7.2.2 Review of Requirements Related to the Products

Requirements related to the product are reviewed during Request for Quotation and Contract Review processes prior to our commitment to supply a product to the customer. Customer Service is responsible to review or coordinate the review of request for quotations, purchase orders, and contracts. The Contract Review process will ensure that:

a) Customer and product requirements are adequately defined and documented. Where no written statement of requirement is available, GM Nameplate will ensure that the order requirements are confirmed, agreed, and documented before acceptance,

b) Any differences in the requirements are resolved,

c) GM Nameplate has the capability to meet contractual requirements,

d) Special requirements of the product are determined,

When product or contract requirements are changed, amendments are made to the relevant documents and are transferred to the concerned functions within the organization. These processes are defined in documented procedures. Records of contract review are maintained.

7.2.3 Customer Communication

GM Nameplate establishes effective methods of communication with our customers, including determining customer requirements, product information, handling of customer inquiries, orders and contracts, and customer feedback including customer complaints.

GM Nameplate further has a communication method established for customer feedback, complaints or return of any nonconforming materials and advisory notices. In general, advisory notices will be communicated under conditions that may warrant.

Reference Document: 01-QP-70.2 Customer Requirements and Communication

7.3 Design and Development

The design and development requirements for products do not apply to GM Nameplate. Products at GM Nameplate are manufactured to customers' design and specifications. Customers are responsible for controlling their product design and evaluating risks associated with those designs. However in order to manufacture customer products, GM Nameplate is required to produce various pieces of equipment and processes. Design of required equipment and processes are not part of the ISO 13485 requirements but the organization will use principles of section 7.3.7 of the Standard to control process design and customer approved changes to products.

Reference Documents: O1-DE-003 Intaq Design Engineering Process and
01-DE-006 Intaq/Functional Part Engineering Change Request/Order

7.4 Purchasing

7.4.1 Purchasing Process

GM Nameplate ensures that all purchased goods and services utilized in the manufacture of GM Nameplate products conform to specified requirements. Through a controlled purchasing process and close working relationships with our suppliers, materials are purchased at the best possible quality, cost, and delivery.

Suppliers are selected on the basis of their ability to meet specified requirements, including quality requirements. Purchasing at GM Nameplates maintains list of suppliers, records of approved supplier evaluations and actions taken for lack of performance.

7.4.2 Purchasing Information

Purchasing documents contain the information necessary to describe the product to be purchased. Where appropriate, purchasing information includes:

a) Requirements for the approval of product, procedures, processes and equipment,
b) Requirements for qualification of personnel,
c) Quality Management System requirements.
d) Identification and revision status of the product, and all applicable specifications, drawings and other relevant data,
e) Change notification and verification

Purchasing documents are reviewed for adequacy prior to their communication to the supplier. Records and documents of relevant purchasing information are maintained for traceability purposes.

7.4.3 Verification of Purchased Product or Service

GM Nameplate maintains documented procedures assuring that incoming materials are inspected and meet specified purchase requirements. Purchased product is verified to ensure that it meets the specified purchase requirements. Verification may include inspection, review of data, and other activities on the part of the GM Nameplate or our supplier. Where GM Nameplate or our customer intends to perform verification at the supplier's premises, the intended verification arrangements and methods are stated in the purchase order.

In the event materials or components are rejected, the procedures assure the segregation of this material. Records of receiving and verification activities are maintained.

Reference Documents: 01-QP.70.4 Purchasing

7.5 Production and Service Provision

7.5.1 Control of Production and Service provision

7.5.1.1 General Requirements

GM Nameplate has developed processes and procedures to ensure that all aspects of production activities are controlled and validated, and that product is properly identified and protected throughout manufacturing and delivery.

Procedures are maintained for planning and carrying out production under controlled conditions, including:

a) Product characteristics information is provided that describe the characteristics of the product,

b) Work instructions describing the performance of the process are available as necessary to ensure safety, quality, and compliance with regulatory requirements,

c) Equipment suitable for the production of the product or performance is used,

d) Availability and use of monitoring and measuring equipment is used to monitor and measure processes and product,

e) Implementation of monitoring and measuring equipment is used to monitor and measure processes and product,

f) Release and delivery activities are defined for the release and delivery of the product, and where applicable, post-delivery activities,

g) Accountability is maintained of all product during manufacturing,

h) Evidence that all production and inspection/verification operations have been completed as planned, of as otherwise documented and authorized

i) Provisions for the prevention, detection and removal of foreign objects

j) Utilities, such as water, compressed air, electricity and chemical products, are monitored and controlled where they affect product quality

k) Criteria for workmanship are provided in the clearest practical way,

l) Process controls and control plans are established where key characteristics have been identified,

m) In-process verification points are identified when adequate verification of conformance cannot be performed at a later stage of production,

n) Tooling is designed, manufactured and used so that variable measurements of the product can be made, particularly for key characteristics,

o) Special processes, where the resulting output cannot be verified by subsequent monitoring and measurement, are validated,

Each order of a product has a unique identification number which is used for traceability purposes. Additionally each production record has the information regarding the amount manufactured.

Reference Document: 01-QP-70.9 Manufacturing Process and Specification Change Control
01-QP-70.5 Product Identification and Traceability

7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 Cleanliness of product and contamination control

Due to the nature of the product manufactured at GM Nameplate, cleanliness of the products and contamination control are not required for the products manufactured at GM Nameplate therefore this requirement is not applicable.

7.5.1.2.2 Installation Activities

Installation activities are not required for GM Nameplate products therefore it is not applicable.

7.5.1.2.3 Servicing Activities

No servicing activities is required for GM Nameplate products therefore it is not applicable.

7.5.1.3 Particular Requirements for Sterile Medical Devices

The requirement in this section does not apply to the products manufactured at GM Nameplate.

7.5.2 Validation of Processes for Production and Service Provision

7.5.2.1 General Requirements:

Processes where the output cannot be verified by subsequent monitoring or measurement are validated. This includes any processes where defects become apparent only after the product is in use or has been delivered. These processes are referred to as special processes.

Validation of special processes demonstrates the ability of the process to achieve the planned results. Requirements for validation and operation of special processes include:

a) Defined criteria for the review and approval of special processes,

b) Approval of equipment and qualification of personnel

c) Use of specific methods and procedures,

d) Requirements for records,

e) Revalidation of the process as necessary.

Additionally when computerized equipment with software is used for production or testing process, GM Nameplate ensures that the software is fully validated prior to initial use of that

software in production or testing of a product. Records of such validations are controlled and maintained**.**

Reference Document: 01-QA-20.2 Process Validation

7.5.2.2 Particular Requirements for Sterile Medical Devices

GM Nameplate does not manufacture, assemble or distribute sterile medical devices, therefore this requirement does not apply.

7.5.3 Identification and Traceability

7.5.3.1 Identification

Product is identified and traceability maintained throughout the manufacturing cycle. Procedures are maintained to provide for:

a) Identification of raw materials and purchased components, including those stored in inventory or released to work orders. Traceability of key raw materials and purchased components, as defined by GM Nameplate procedures, is maintained.

b) Identification of each production order with a unique number that serves as a lot number. The product and its associated work order ticket are identified with this number throughout production, inspection and test, packaging and shipment.

c) The status of product with respect to inspection and test requirements is maintained to ensure that only product that has passed all of the planned inspection and test activities is available for shipment,

d) Order tracking, accomplished with a barcode routing system recording order movement from station to station,

e) Upon completion of production, products are packaged and identified by customer purchase order number and part number.

f) Maintenance of the identification of the configuration of the product through work order tickets and controlled drawings, specifications and other documentation. Records are maintained to document any differences in the actual configuration and the agreed upon configuration.

g) Documented procedures and controls where acceptance authority media are used (stamps, electronic signatures or passwords, etc.

7.5.3.2 Traceability

7.5.3.2.1 General

GM Nameplate's documented procedure provides details on traceability of the product. In general, GM Nameplates provide for the following levels of traceability:

a) Identification of the product so that the identification and traceability are maintained throughout the product life,

b) Traceability of all of the products manufactured from the same batch, including the destination (delivery, scrap) of all of the products from the same batch,

c) Traceability of components in an assembly,

d) A sequential record of the manufacturing and inspection processes used in the production of the product.

Reference Document: 01-QP- 70.5 Product Identification and Traceability

7.5.3.2.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices

GM Nameplate *does not produce, manufacture, or assemble any medical devices that, by definition, meet the specifications for active implantable and/or implantable medical devices by itself.*

7.5.3.3 Status Identification

GM Nameplate identifies the product status throughout the manufacturing/ assembly, inspection, packaging, storage and delivery process. Throughout the manufacturing/ assembly in-process and final inspection processes, the work instructions identify the status of the product.

Each process is signed or initialed when completed. If finished product is entered into inventory, the inventory record and labeling will identify the lot number. All information specific to finished product is maintained in production records by lot number.

Reference Document: 01-QP-70.9 Manufacturing Process and Specification Change Control
01-QP-70.5 Product Identification and Traceability
01-QP-80.3 Monitoring and Measuring of Product

7.5.4 Customer Property

GM Nameplate occasionally works with customer owned and supplied materials and equipment, and also intellectual property (e.g., specifications, drawings, digital media and personal data). Customer property is verified, stored, and maintained as specified by the customer or, when not specified, in the same manner as GM Nameplate property. Any property that is lost, damaged or otherwise found to be unsuitable for use shall be reported to the customer and records maintained.

Reference Document: 01-QP-70.6 Control of Customer Property

7.5.5 Preservation of Product

GM Nameplate maintains documented procedures for preserving the conformity and quality of products from the time of receipt during the internal processing and delivery to our customers.

Requirements for preservation of product are consistent with product specifications and contract and regulatory requirement.

Procedures include provisions for identification, handling, storage, packaging, and delivery.

Products manufactured at GM Nameplates are not susceptible to damage or deterioration due to ambient environmental conditions therefore no special storage condition is required

Reference Document: 01-QP-70.7 Preservation of Product
01-QP-80.6 Corrective and Preventive Action

7.6 Control of Monitoring and Measuring Devices

GM Nameplate determines the monitoring and measurement to be undertaken and the monitoring and measurement devices required to provide evidence of conformity of products to determined requirements.

GM Nameplate maintains documented procedures to ensure that monitoring and measurement are adequate to provide evidence of product conformity to the specification and requirements. This includes details of the equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Devices used to monitor or measure product, including test software or comparative references are controlled by:

a) Determining required monitoring/measurement and suitable devices and ensuring consistency with monitoring and measurement requirements,

b) Device calibration at specified intervals against of NIST-traceable or equivalent standards, where no such standards exist, the basis used for calibration is documented.

c) Documenting any required adjustments and recording,

d) Identifying calibration status,

e) Safeguarding devices from inadvertent adjustments,

f) Protection from damage and deterioration,

g) Assess and document the validity of product tested with equipment found to be out of calibration, and take corrective action, as required.

Records of measurement and monitoring equipment calibration, recalibration, and adjustments are maintained. Equipment that cannot be calibrated or is designated as "for reference only" are labeled as such.

Reference Document: 01-QP-70.8 Control of Monitoring and Measuring Devices

8 Measurement, Analysis and Improvement

8.1 General

GM Nameplate maintains documented procedure for development and implementation of plans for monitoring, measurement, analysis and improvement processes using appropriate statistical tools and techniques to:

a) Demonstrate the conformance of product requirements,

b) Ensure the conformance of our Quality Management System,

c) Maintain the effectiveness of the Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Feedback

GM Nameplate monitors information related to our customer's perception as to whether we have met their requirements. Documented procedures define the methods for obtaining and using this information. Methods include:

a) Customer surveys. Corporate Sales and Marketing coordinates with each division of GM Nameplate to perform annual customer surveys,

b) Customer feedback and complaints. A customer comment form is maintained on the GM Nameplate website. Customer complaints received through other means are recorded in a customer complaint log,

c) Customer returned products,

d) Customer-supplied performance reports.

These records are periodically reviewed and monitored for possible trending that may evidence recurring or consistent problems or issues. The feedback Services are also used to provide early warning of any quality problems and input into corrective and preventive action to be taken.

Reference Document: 01-QP-80.1 Customer Satisfaction

8.2.2 Internal Audit

Internal audits are conducted on planned intervals to determine if the Quality Management System complies with the required standard, customer, and/or regulatory requirements and to determine if it is effectively implemented and maintained.

Audit schedules are based on considerations of the importance of processes to the objectives of GM Nameplate, and the results of previous audits.

Audits are carried out by competent, trained personnel who are not directly responsible for the audited activity. Auditors do not audit their own work. The Director of Quality may delegate an audit to any trained employee at the company. Internal audits may be subcontracted to a qualified third party organization.

Management is responsible to ensure that the corrective actions are taken on a timely manner and follows up to ensure the elimination of detected nonconformities identified during the internal audit and the effectiveness of these action.

Records of audits and corrective actions and preventive actions are maintained.

Reference Document: 01-QP-80.2 Quality Audits

8.2.3 Monitoring and Measurement of Processes

Quality Management System processes are monitored and measured to determine ability of the processes to achieve the planned objectives. Methods used to monitor and measure processes include:

a) Customer satisfactions results,

b) Internal audits,

c) Product quality performance measurements,

d) Process efficiency measurements,

e) On-time delivery performance.

Corrections and corrective actions are taken commensurate to the effect of the process nonconformance on the conformity of the product when the processes do not achieve the planned results.

8.2.4 Product Monitoring and Measurement of Product

8.2.4.1 General Requirements

Product characteristics are monitored and measured to verify that product requirements have been met. An appropriate selection of both variable and attribute characteristics are monitored and measured at locations established during the planning of product realization processes. Work instructions specify inspection at each location. The work order ticket and part drawings convey product specific inspection requirements.

Records of inspections and testing are maintained as evidence of conformity with the acceptance criteria. Records identify the person authorizing release of the product. Product is not released until all of the planned activities for product realization have been satisfactorily completed.

Reference Document: 01-QP-80.3 Monitoring and Measuring of Product

8.2.4.2 Particular Requirement for Active Implantable Devices and Implantable Devices

GMP Nameplates does not manufacture, assemble or distribute active implantable devices or implantable devices.

8.3 Control of Nonconforming Product

Documented procedures define the control of product that is found nonconforming, detected at any stage of manufacturing from incoming inspection through shipping, and product returned by the customer. These procedures and controls prevent the unintended use or delivery of nonconforming product, including raw materials, components, subassemblies, and finished items.

When non-conforming product is detected after delivery or use has started GM Nameplate will take appropriate actions to the effects, or potential effects, of the nonconformity. Delivered nonconforming product is reported to the customer in a timely manner.

Dispositions applied may be: rework, use as is (only when the nonconformity does not result in a departure from the customer-specified requirements or is authorized by customer), repair, scrap or return to supplier.

Nonconformity that can be corrected is subject to re-verification and the same type of inspection and approval as the original job.

Prior to authorization and approval of reworked products, potential adverse effect of the rework on the product will be identified and documented. All reworks are documented on appropriate job jacket or work instructions. Reworked documents are maintained with the original job jacket or batch for that product.

Records of nonconformities and subsequent actions taken, including concessions are maintained.

Reference Document: 01-QP-80.4 Control of Nonconforming Product

8.4 Analysis of Data

Data is collected and analyzed to evaluate the suitability and effectiveness of the Quality Management System and to evaluate where improvement of the effectiveness of the quality management system can be made.

Categories of data collected and analyzed include:

a) Product Quality – Quality Assurance ensures that quality data, including the costs of nonconformance, are collected and reported. Quality reports are reviewed by executive and departmental management. Quality data are also analyzed for trends and presented in Management Review meetings by Quality Assurance.

b) Process Performance – Data related to process performance, including variations from planned efficiencies and schedules, are collected, and reviewed by department managers. Performance and trends are compared to appropriate goals and company benchmarks. Department managers analyze variances, identify problems, and implement solutions to maintain performance goals and improve performance.

c) Supplier Performance – Purchasing and Quality Assurance ensure that supplier performance data are collected and reported. Performance data include on-time delivery and conformance to quality requirements. Purchasing and Quality Assurance analyze supplier performance and take appropriate actions to maintain and improve performance goals.

d) Customer feedback – Data related to customer satisfaction levels and complaints are collected by Sales and Marketing, Customer Service and Quality Assurance, and reviewed by executive management.

Records of the results from data analysis are maintained.

8.5 Improvement

8.5.1 General

Improvement of the Quality Management System is driven through the quality policy and quality objectives. Opportunities for improvement are identified through management review, audits, corrective and preventive action processes, and analysis of data. Improvements shall be monitored and evaluated for effectiveness of the quality management system.

GM Nameplate maintains documented procedure for the issue and use of advisory notices for medical devices, as applicable and when needed. This documented procedure is capable of being implemented at any time.

Records of customer complaints and subsequent investigations are maintained. When investigation determines that the activities outside GM Nameplate premises contributed to the customer complaint, relevant information is communicated between GM Nameplate and the customer. Documented procedures stipulate that customer complaints are followed by corrective and/or preventive action and if not, the justification is recorded.

GM Nameplate does not manufacture finished medical device product therefore will not receive the adverse event report from the end user, therefore if any report received it will be forwarded to the customer for proper action. However GM Nameplate maintains a procedure for compliance to specific national and international regulatory requirements for reporting and notifying appropriate authorities of those adverse events that meet the criteria for required reporting.

8.5.2 Corrective Action

GM Nameplate maintains a documented procedure to ensure that actions are taken to eliminate the cause of nonconformities and follow up action are performed to ensure that action taken will effectively prevent recurrence. The need for corrective action, actions considered and actions implemented are commensurate with the magnitude and risks associated with the nonconformities. The corrective action may apply to suppliers, product quality and production process, customer complaints, and internal audit findings.
Records of the results of the investigation, corrective actions taken, and follow-up actions are maintained. Results of Corrective Actions and their effectiveness are reviewed by management in Management Review meetings.

8.5.3 Preventive Action

Preventive actions are taken to prevent potential nonconformities. Actions taken are appropriate to the effects of the potential problems. The determination of need for preventive action includes review and analysis of processes, quality data, trends, customer complaints and feedback, and audit results.

Records of the results of the investigation, preventive actions taken, and follow-up actions are maintained. Results of Preventive Actions and their effectiveness are reviewed by management in Management Review meetings.

Reference Documents: 01-QP-80.6 Corrective and Preventive Action