



# NDC Quality Manual

## 1 Introduction to Nitinol Devices & Components (NDC)

### 1.1 About NDC

NDC is a developer and manufacturer of Nitinol based components for both medical and commercial applications. NDC is located in Fremont, California.

### 1.2 Registrations

ISO 13485: 2003 BSI # FM 78817, NDC, Fremont, Ca

US FDA Registration # 2951217: NDC, Fremont, Ca - Inactive

State of California DHS # Pending (submitted for registration): NDC, Fremont, Ca

### 1.4 References

ISO 13485: 2003: "Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes"

ISO 14971:2000, Medical Devices - Application of risk management to medical devices

Title 21 CFR Part 820, Food and Drug Administration, "Quality System Regulation"

Title 21 CFR Part 11, Food and Drug Administration, "Electronic Records; Electronic Signatures"

Ministry of Health, Labor and Welfare (MHLW) Ordinance No. 169, 2004

## 2 Scope

### 2.1 Application

NDC designs, develops and manufactures medical device components and raw materials (for both medical and non-medical uses).

### 2.2 Exclusions

The exclusions for the business are as follows:

1. The company does not provide installation or servicing for the customers. The installation and servicing requirements of Sections 7.5.1.2.2 Installation Activities and 7.5.1.2.3 Servicing Activities are excluded from this quality system.

### 3 Quality System Overview

#### 3.1 NDC Quality Policy

Everyone at NDC is responsible for the quality of his or her work.

NDC will achieve this commitment by:

- Meeting regulatory requirements and integrating quality through innovation, talent, design and profound process knowledge.
- Focusing talents on monitoring and continuously improving design, quality systems and processes to better serve our customers, the medical community and meeting or exceeding worldwide quality and regulatory requirements.

#### 3.2 NDC Quality Objectives

NDC considers the safety, efficacy and quality of our products to be of utmost importance. These high-level quality objectives are derived from the Quality Policy and are the foundation from which all quality goals and activities are developed. The Quality Objectives and goals or changes to them are generated during the Management Review meetings and recorded on management review meeting notes. In general, the Quality Objectives include Product Performance, Customer Communication (Complaints, returns, delivery performance), Supplier management, Training, Corrective and Preventive Actions, and Environmental, Health and Safety management and others.

#### 3.3 Organizational Structure

The NDC organizational structure is maintained as a separate document. An approved copy is maintained by the Quality Systems department.

### 4 Quality Management System

#### 4.1 General Requirements

The NDC Quality Management System is established to implement the requirements of ISO 13485:2003, USFDA 21 CFR Part 820, Quality System Regulation and other standards, and to establish policies and procedures that support the objectives of the company.

The Management with Executive Responsibility approves initial release and changes to this document through the Engineering Change Order (ECO) process.

The process needed for the management of the QMS consist of:

- Product Realization, where new product is developed based on customer needs and transferred to manufacturing,
- Delivery to customers and
- Using customer feedback to make improvements to the Product Realization process.

In addition, Internal Audits and Management Review processes are used to evaluate the effectiveness of quality system and drive improvement by monitoring and measuring the outcome of these processes.

Management Review also ensures availability of adequate resources and technology to support the QMS.

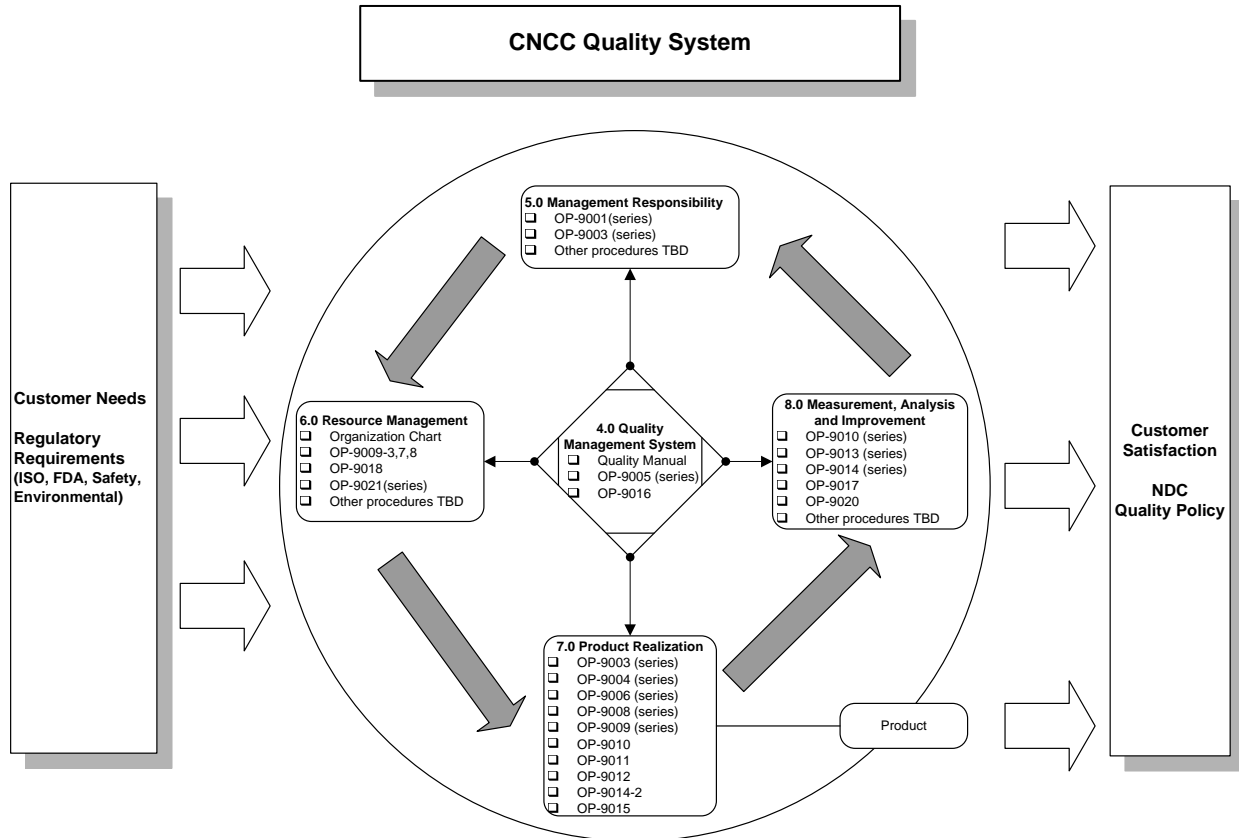
This Quality Manual provides policy and other top-level guidance (Level I), and makes reference to Operating Procedures for detailed procedures on the operation of the System (Level II). Detailed procedures for manufacturing and supporting activities are found in Travelers, Work Instructions, Inspection Plans and other Level III documents.

The authority to perform the tasks identified in this document and other Quality System documents may not be delegated unless specifically stated otherwise. Such delegation is to be in writing, and the overall responsibility for proper performance of the task remains with the individual referred to in the documentation.

The scope of the quality system covers production of standard product and all supporting activities. Design and development activities are also covered.

The responsibility for the NDC quality system has been assigned to Management with Executive Responsibility (MWER). The Vice President of Quality Assurance has been designated by the President of NDC to be the Management Representative with full responsibility and authority for establishing and maintaining the quality system in accordance with Quality System requirements.

The process depicted below provides an overview of the NDC Quality System model. The closed loop process ensures that NDC has not only established, but also improves processes and practices on a continuous basis.



## 4.2 Documentation Requirements

### 4.2.1 General

The NDC quality policy is stated in this Quality Manual. Top management identifies quality Objectives that meet the requirements of the quality policy annually. The quality objectives are documented in the Management Review meeting minutes.

The NDC Quality Manual is the top-level document that describes the overall quality system in accordance with the stated quality policy, ISO 13485: 2003 and 21 CFR Part 820.

The NDC Operating Procedures (OP) and Quality Plans are the next level of documentation. Quality Plans provide a summary of all quality activities in support of a product or product line. OPs establish company-wide procedures and requirements. They are generally non-technical and may use a variety of formats, such as flow charts. The OP's are numbered in accordance with the twenty elements of ISO 9001:1994. Each section of this quality manual references the applicable OPs.

The third level of documentation include (but not limited to):

Travelers establish the process flow and processing instructions for items produced in the facility. Verification activities are included or incorporated as steps in the process flow defined by the traveler. Detailed instructions are normally incorporated in Work Instructions, which are referenced on the Traveler.

Work Instructions (WI) provide detailed instructions that are too lengthy to be included on a traveler or other document. Work Instructions may also be created for detailed or step-by-step instructions for a process whose policies are described in an OP.

Inspection Plans identify specific inspections or tests to be performed, sampling plans, and the data or other records to be generated. Detailed inspection methods are documented in Work Instructions.

Inspection Data Sheets may be developed to record specific measurements or other quality data.

Product drawings define company products, including dimensional, material, and functional characteristics.

Tooling drawings define key tools, dies, and other production or test/inspection equipment.

Product Specifications may be created for products that are not suited for drawings.

Purchase Specifications define purchased items or material not appropriate for drawings.

Workmanship Standards provide examples of qualitative references.

Forms are used to define some activities and collect records.

Lab Notebooks record design and development activities.

Protocols and associated Reports define test and validation plans and their results.

Approved Supplier List shows the suppliers that may be used to purchase inventory items and certain key manufacturing materials.

The last level of documentation are quality records. These documents serve as evidence of the performance of all activities that impact product quality.

Device Master Records (DMRs) containing product specifications, procedures for manufacture and inspections consist of the Level III documents and Level IV records (drawings, work instructions, specifications, travelers, etc.).

Device History Records (DHR) also known as lot history folders at NDC, consist of process/manufacturing/inspection records for each lot.

Design History File (DHF) contains design and development history for product, such as product requirements, design and development plan,

FMEA/risk analysis, quality plan, design change records, validation documents etc.

#### 4.2.2 Quality Manual

The NDC Quality Manual (this document) defines the policies, application, scope, exclusions and documentation of the quality management system.

#### 4.2.3 Control of Documents

Documents that define products, processes, and the quality system are approved before controlled release and distribution. Documents are available for use in the locations required as well as online. Obsolete documents are removed when superseded. External documents such as industry or agency standards and customer drawings are controlled. Quality Assurance Document Control provides document control services; however, all employees are responsible for using correct documents, at the prescribed revision level, at all times.

Obsolete documents are retained for a period specified in the OP-9016, Quality Records.

External documents are controlled and issued to ensure use of correct documents and current revisions. Such documents include external customer documents (such as drawings and specifications) and other external documents, such as industry standards.

##### 4.2.3.1 Approval and issue

Documents under ECO control are approved by the individuals assigned per OP-9005, Document Control, using the Engineering Change Order (ECO) system. The Development Change Order (DCO) is used to approve changes in development items. Controlled copies are issued to the individuals or work areas that require them for day-to-day use. Uncontrolled reference copies may also be provided. Control status is indicated by the use of stamps with red ink on hard copies. Indexes are maintained. Documents are also maintained on-line as read only in the document control system.

##### 4.2.3.2 Initial release and changes

With the exception of Engineering Memos and Technical Reports, initial releases and changes are processed using the Engineering Change Order (ECO) or the Development Change Order (DCO). The changes are reviewed and approved per OP-9005 series, Document Control procedures. Changes to associated documents are initiated as part of the ECO/DCO approval cycle. A history of changes is maintained for approved ECO/DCO documentation.

#### 4.2.4 Control of Records

Quality records are created and maintained to provide documented evidence of the conformance of products and systems to specifications and process requirements. The records are identified, indexed, and stored to prevent deterioration and provide access in a reasonable period of time. Secrecy, Confidentiality, and Nondisclosure Agreements may govern customer access to records.

##### 4.2.4.1 Identification of Quality Records

All documents that establish the history of the product and supporting systems are considered quality records. Exclusions include production or inspection tally sheets that are summarized on other records.

##### 4.2.4.2 Filing and Storage

For product, quality records are filed with the Lot History File. System records are filed by type.

##### 4.2.4.3 Retention

Records on all media will be maintained that (1) are required by law; (2) necessary to support the orderly operation of the Company; or (3) provide the basis for recovery from a disaster. All other records will be destroyed. Retention guidelines are stated in OP-9016, Quality Records.

#### 4.2.5 Other Organizations Covered by the Quality Management System

In some cases, NDC provides quality system support for external companies. In these cases, the quality system requirements are applied to other companies with variations as authorized by those companies. The variations from the NDC quality system are to be documented in the using-company's Quality Manual.

- 4.2.5 References for this section
- OP-9005, Document Control
  - OP-9005-1, Documentation Practice
  - OP-9005-4, Temporary Process Modification
  - OP-9005-5, Customer Document Control
  - OP-9005-7, Software Control – Manufacturing & Test /Inspection
  - OP-9005-10, Document Changes Approval and Distribution
  - OP-9005-11, Device Master Record and Quality System Record Process
  - OP-9016, Quality Records

## 5 Management Responsibility

### 5.1 Management Commitment

The progress of the business and the effectiveness of the quality system are reviewed on a regular basis by Management with Executive Responsibility.

Management with executive responsibility (executive management) is responsible for establishing, implementing, and continuously improving the quality system.

Personnel and other necessary resources are provided to accomplish the goals of the quality system.

There are several processes by which executive management communicates to the rest of the company regarding customer, regulatory and statutory requirements and the importance of meeting these requirements.

Informational meetings, plant meetings are conducted periodically.

Training is conducted on a regular basis according to the requirements specified in the training procedure, this includes training to regulations, safety etc. New employees go through a series of training, so they have a thorough understanding of the company, product, customer and regulatory requirements.

Management Reviews, internal and external audits are conducted periodically to ensure that the Quality System is effective.

Management Review is the mechanism by which opportunities to improve are identified and resources are allocated to achieve those improvements. Quality objectives are defined at these reviews. Personnel and other necessary resources are provided to accomplish the goals of the quality system.

### 5.2 Customer Focus

In addition to communicating the importance of meeting customer requirements, top management ensures that customer requirements are determined, understood and met. Processes have been established to ensure device customer safety and efficacy.



Within the scope of the quality management system, contracts and agreements are defined and reviewed between NDC and its customers for work to be performed or product to be delivered. Requests for Quotations (RFQ) and Purchase Orders (PO) are reviewed to assure that requirements are defined and understood, and that NDC can meet the requirements.

The individual receiving the RFQ or PO (the Recipient) sponsors a Contract Review. Representatives of Sales/Customer Service, Operations (production), QA, and the Manufacturing Engineering participate in the Review, as necessary. Others may be included as needed.

The review assures that the customer's requirements are defined, documented, and understood and that they can be met. Reviews include as a minimum: specification requirements, documentation, manufacturability, price and delivery. Differences and/or specification conflicts are resolved before approving the Contract Review and accepting an order.

Initial reviews are approved by Managers, Directors, or higher levels in the organization. Repeat orders with previously reviewed requirements may be reviewed and approved by the Recipient. Results of the Contract Review are documented and maintained as records and are filed by Sales/Customer Service in the Customer Order File.

### 5.3 NDC Quality Policy

The NDC Quality Policy is defined in Section 3.1 of this Quality Manual. The quality policy is communicated and understood within NDC and is reviewed periodically by top management.

The quality objectives derived from the quality policy are reviewed annually and updated as needed by top management to maintain effectiveness of and compliance to the quality management system. (Section 3.2 of this Quality Manual)

### 5.4 Planning

#### 5.4.1 Quality Objectives

The company management team is responsible for setting quality objectives and goals for the company. Functional Managers establish goals and objectives that are aligned with company goals for their departments.

#### 5.4.2 Quality Management System Planning

The planning for Quality Management System is carried out by executive management during management review meetings. Quality objectives are set and reviewed during these meetings. When a change is made to the quality system as a result of an internal audit or management decision, it is reviewed for effectiveness and appropriate justification and approvals are required to implement the change.

### 5.5 Responsibility, authority and communication

The Company is organized as shown on the NDC organization chart. Approved organization charts are maintained by the Quality Systems department. Some individuals perform multiple roles; however, the roles and responsibilities relating to quality are clearly defined in later sections of this Manual, job descriptions, or in other procedures. Independence and authority necessary to manage, perform, and assess tasks affecting quality is maintained by top management.

Job descriptions are assigned by department managers, and are available in the manager's offices. Local supplementation by individual supervisors is permitted as required.

#### 5.5.1 Responsibility and Authority

##### 5.5.1.1 Executive Management

Establish and support the quality policy by providing the necessary resources.

Establish quality goals and objectives for the company.

##### 5.5.1.2 Engineers

###### 5.5.1.2.1 Process Engineers

Establish and document production processes that consistently meet product requirements.

Install and qualify/validate production processes.

Train, verify, and certify skills of operators on assigned processes.

Review and approve process and supporting documents for initial release and changes.

###### 5.5.1.2.2 Product (Design) Engineers

Coordinate functional and other technical requirements with customers or design sponsor.

Design and initiate specification documentation for NDC-designed products.

Review and approve product and supporting documents for initial release and changes.

Coordinate Design Control activities on assigned products.

Initiate travelers and other required documents for prototype or developmental products.

#### 5.5.1.2.3 Manufacturing Engineers

Support ongoing manufacturing, through capability and quality improvement activities.

Initiate, review, and approve manufacturing and supporting documents.

Maintain validation status of processes in assigned areas.

#### 5.5.1.3 Operations Vice-President

Management of planning, throughput, production resources, process improvement activities for manufactured products and other requirements as necessary.

#### 5.5.1.4 Operations Manager

Maintain positive identification and traceability of product in the areas managed.

Manage production resources.

Monitor and control production processes.

Implement production documentation.

Assign trained/certified personnel to standard production processes.

Initiate production travelers for standard products.

Facilities Management for NDC building

Report utilities usage and cost to executive management

Manage Safety and Environmental compliance matters

#### 5.5.1.5 Vice President, Quality Assurance and Regulatory Affairs

Management Representative for NDC reports directly to the President of NDC.

Coordinate and manage company quality assurance and regulatory issues.

Establish and maintain the quality management system.

Develop Quality Plans for principle products and product lines.

Develop Inspection Plans and supporting documents that specify inspection and test requirements and sampling levels.

Maintain positive control of nonconforming material and product.

Coordinate and carry out supplier quality assessments.

Maintain the calibration system.

Maintain the document control system.

Initiate and monitor corrective/preventive actions.

Review and analyze returned material.

Assess and improve measurement capability.

Coordinate internal audits and associated corrective actions.

Prepare certifications and other required quality documentation in support of shipping.

Qualify and approve personnel performing verification activities.

#### 5.5.2 Management Representative

The Vice President, Quality Assurance and Regulatory Affairs, is the company's Management Representative. The Management Representative is responsible for:

- Acting as executive management's agent in establishing, implementing, maintaining, the effectiveness of and improving the quality system;
- Reporting the performance of the quality system and any need for improvement to executive management; and
- Promote awareness of regulatory and customer requirements throughout NDC; and
- Serving as the company's liaison with customers and other outside concerns on matters related to product quality and reliability.

#### 5.5.3 Internal Communication

Management Indicators are established by Management with Executive Responsibility to provide visibility of key operations and performance. Indicators are added, deleted, and modified to suit current conditions and areas of emphasis. The indicators are generated periodically, distributed electronically and hard copies are also posted.

On a periodic basis, Management with Executive Responsibility will disseminate information regarding the state of the business.

### 5.6 Management Review

#### 5.6.1 General

Executive management, and others as required, formally reviews the quality system for compliance and effectiveness at least quarterly. The

Vice-president of Quality Assurance and Regulatory Affairs (or delegate) is responsible for calling and facilitating the review.

Management Review Meeting Minutes are prepared and circulated by the VP QA/RA (or delegate) as required to provide pertinent information regarding quality of product and services or the effectiveness of the quality management system.

Management Indicators are established by Management with Executive Responsibility to provide visibility of key operations and performance. Indicators are added, deleted, and modified to suit current conditions and areas of emphasis.

#### 5.6.2 Management Review Input

On a periodic basis, the VP QA/RA, or designee will call a Management Review Meeting for the group of people identified as Management with Executive Responsibility. Others may be invited to participate as required.

The agenda includes the topics such as Management Indicators, customer service and feedback, audit results, corrective and preventive action. Other topics may be added as deemed appropriate.

#### 5.6.3 Management Review Output

The VP QA/RA or designee takes minutes of the meeting including a record of those attending, action items assigned, progress on ongoing actions, recommended improvements to product related to customer requirements, quality system and processes, resource needs and other pertinent summary information. A management review report is generated for each meeting and approved by Management with Executive Responsibility. Unless otherwise indicated, the report should include a statement to the effect that the Quality System is suitable and effective based on information reviewed and actions taken or assigned.

#### 5.7 References for this section

OP-9001, Management Review

OP-9001-1, Regulatory Agency Inspection

OP-9001-3, Environmental, Safety and Health Management

OP-9003, Contract Review

## 6 Resource Management

### 6.1 Provision of resources

#### 6.1.1 General

Top Management determines and provides the resources necessary for the implementation, maintenance, and continual improvement of the entire quality system. Top Management assigns appropriate resources to enhance customer satisfaction through meeting customer requirements.

### 6.1.2 Resource Determination

Top Management determines appropriate resource needs during periodic business reviews and during Management Review. Resource needs are established through consideration of customer satisfaction and quality management improvements. Top Management considers all resources necessary to accomplish these needs, including personnel, facilities, equipment and finances.

## 6.2 Human Resources

### 6.2.1 General

#### 6.2.1.1 Qualification Documentation

Written job descriptions are in place for all activities affecting product quality to document the qualifications and duties of the positions determined to be necessary by Top Management.

#### 6.2.1.2 Assignment of Resources

Resources are assigned based on experience, education, skills and training to appropriate tasks to meet established business and quality objectives.

### 6.2.2 Competence, Awareness and Training

#### 6.2.2.1 Competence

Competency requirements are determined for each position through establishment of appropriate performance goals for the written job description. Performance monitoring and performance management are integrated into operations to ensure that assigned personnel are fulfilling requirements satisfactorily. In the case where personnel are not performing satisfactorily, performance management tools and appropriate training are used to correct unsatisfactory performance.

#### 6.2.2.2 Awareness

The required training for each position includes training on the impact of their position on quality objectives and the quality management system.

#### 6.2.2.3 Training

Training needs are documented for each position via supervisor input and specific minimum requirements detailed in the training operating procedure. Completion of training requirements is verified prior to assignment to work. Training activities include a verification of training effectiveness and appropriate refresher training.

The training procedure (OP-9018) ensures that personnel understand both the job function and the GMP requirements, including how the job relates to the overall quality system. In

addition, personnel are trained to ensure that the consequences of improper performance are understood so that employees are aware of defects that they should look for and of the effect their actions can have on the safety and effectiveness of the device.

Training Records for both internal and external training are maintained. The Human Resources department maintains records of education, skills and experience in personnel files.

### 6.3 Infrastructure

Top Management establishes the facilities, workspace, hardware, equipment, software and supporting services necessary to achieve conformity of product. These requirements are monitored through various metrics to ensure adequacy and modified when appropriate to ensure conformity of product.

### 6.4 Work Environment

Top Management is responsible for establishing appropriate work methods, safety rules, protective equipment and ergonomics to ensure conforming product. The adequacy of these controls is periodically assessed and corrective actions taken as needed.

### 6.5 References for this Section

OP 9001,	Management Review
OP 9004-10,	Quality Plan
OP-9009,	Process Control
OP-9009-1,	Preventive Maintenance
OP-9009-2,	Manufacturing Process Validation
OP 9009-3,	Workstation Practices
OP-9009-4,	Manufacturing Tooling Qualification
OP-9009-5,	Laser Processing Area Operations
OP-9009-7,	Hazardous Energy Control (Lockout/Tagout)
OP-9009-8,	Contractor Safety Program
OP-9009-9,	Process Improvement Control
OP-9009-12,	Software Validation
OP-9011,	Calibration - Inspection, Measuring and Test Equipment
OP-9014,	Corrective Actions
OP-9018,	Training

## 7 Product Realization

### 7.1 Planning of product realization

Quality planning occurs throughout the product life cycle. Typical planning activities and the responsible people are defined in detailed Operating Procedures and Quality Plans and include:

- Review and documentation of customer requirements, including Design Inputs for new products.
- Identification and acquisition of necessary resources (equipment, personnel and associated skills, processes, controls, monitoring devices, inspection and test equipment, etc.).
- Identification of advanced measurement requirements that must be developed or acquired.
- Risk management throughout the product realization cycle.
- Identification of verification activities at appropriate steps in the process.
- Identification of Design Verification and Validation activities
- Establishment of workmanship standards.
- Identification of required records (including records of risk management activities).
- Identification of certification and test report requirements.

Inspection and testing is planned and conducted when purchased materials and components are received, at key stages of processing, and before release of product. Inspections are conducted according to approved plans. Qualified individuals from any organization may perform inspections and record results. Inspections may utilize data prepared by others to make decisions when specified in the Inspection Plan. Employees of QA/QC, or those specifically delegated, must close out all Inspection Plans. Records are made of inspections specified in the Inspection Plan.

## 7.2 Customer related processes

### 7.2.1 Determination of requirements related to the product

Within the scope of the quality management system, contracts are defined as any agreement between NDC and a customer that defines work to be performed or product to be delivered. Requests for Quotations (RFQ) and Purchase Orders (PO) are reviewed to assure that requirements are defined and understood, and that NDC can meet the requirements.

For new product development design requirements or inputs are collected from many sources, including customers, suppliers, professionals in the field of use, similar products, and others. The inputs are documented, subject to initial approval, and modifications are approved at later reviews as required.

### 7.2.2 Review of requirements related to the product

Contract review assures that the customer's requirements are defined, documented, and understood and that they can be met. Reviews include as a minimum: specification requirements, documentation, manufacturability, price and delivery. Differences and/or specification conflicts are resolved before approving the Contract Review and accepting an order.



A Specification Review is conducted when a technical review of customer specifications is required.

Records of Contract Review and Spec reviews are maintained.

#### 7.2.3 Customer communication

If customer requirements or specifications cannot be met, the information is communicated to the customer. Amendments to the contract may be made with the approval of the customer. Where no change agreements are in place, proper notification and authorization is required prior to implementation of improvements.

Where a component is included in a finished medical device sold by medical device companies, the company will respond to requests and inquiries in support of the complaint investigation led by the seller. Such requests are entered into the complaint system for tracking and into the Corrective and Preventive Action system if action is required.

The complaint handling procedure is also used to manage the resolution of complaints received on company products that are not finished medical devices.

### 7.3 Design and Development

As a developer and manufacturer of components for both medical and commercial applications (with the exception of NDC finished devices), NDC does not complete full design and development cycles for new products. The designs typically originate at other sites and the overall design control responsibility lies with them. However, within the scope of our involvement with the overall development project, NDC will adhere to design control procedures. Where NDC yields to another site's design control procedures, a copy of the Design History File (DHF) index or table of contents will be maintained at NDC.

In the case of NDC finished devices (NDC sponsored design), Design Control procedures including Design Verification and Validation procedures are followed.

The company Design Control/New Product Development procedures are intended to balance the freedom to innovate and the discipline required to consistently meet customer and regulatory requirements. Design activities before the formal documentation of Design Inputs are at the discretion of the engineer, and records are kept in laboratory notebooks. After the formal establishment of the Design Inputs, design activities are planned, controlled, and regularly reviewed/approved. The Design History File is maintained by the design team leader during the development process and then turned in to Document Control for archiving after the project is complete.

The procedures apply to design activities for which NDC is solely or partly responsible. For those design activities in which NDC is supporting other companies, the procedures of the sponsoring company may be used.

### 7.3.1 Design and development planning

The new product development team leader is responsible for documenting and updating the overall plan, which identifies activities, schedules, and responsibilities. The new product development team leader coordinates organizational and technical interfaces, including information transfers and reviews.

### 7.3.2 Design and development inputs

Design inputs are collected from many sources, including customers, suppliers, professionals in the field of use, similar products, and others. The inputs are documented, subject to initial approval, and modifications are approved at later reviews as required.

Product requirements are defined, documented and approved. The requirements are generally maintained in the Design History File (DHF) during the development phase.

### 7.3.3 Design and development outputs

Design outputs are documented and are compared to design inputs to assure that input requirements are met. Design outputs include, but are not limited to, design and material specifications, testing and technical reports, drawings, work instructions and quality assurance procedures. Design outputs are reviewed and approved during design reviews that occur at various stages of the design effort, but particularly before sales release. Design output documentation is contained in the Device Master Record (DMR).

### 7.3.4 Design and development review

Design Reviews are held at key milestones. Individuals and management with responsibility for design activities participate and approve the results and plans. Minutes of the reviews are published, and identify all outstanding action items and who is responsible for resolving them. Initial and final reviews are required, but others may be scheduled as necessary, depending upon the scope of the project.

An initial review is done that formally establishes the basic concept feasibility, Design Inputs, and assigns resources.

An intermediate review may be done during product design and process development. The review confirms that design output meet design input requirements. For medical applications, a review is done prior to beginning human-use trials (first-in-man or clinical use). The review specifically focuses on confirmation of product safety.

A final review is done before product launch (sales release). The review confirms that Design Outputs meet Design Input requirements.

For NDC sponsored designs involving NDC controlled clinical studies, a Clinical Release Design Review is also required to assure the safety of the pre-production material for human use.

#### 7.3.5 Design and development verification

Design verification is the confirmation that the design output is appropriate to produce a product that meets product specification requirements. Records of verifications performed are approved and maintained indicating the acceptability of inspection and test results.

#### 7.3.6 Design and development validation

Design validation means establishing by objective evidence that device specifications conform with user needs and intended use. Records of design validations are approved and maintained indicating the acceptability of the studies.

#### 7.3.7 Control of design and development changes

Changes are evaluated as to the impact on the design's safety and efficacy as well as on regulatory strategy / issues. The appropriate verification / validation, review, and approval of the change is required before the implementation of the change. Design changes are documented and maintained in the Design History File.

#### 7.3.8 Design and development transfer

Design transfer is the process of assuring that the design is correctly translated into production specifications. All specifications released to production are approved and under formal change control. Operators are trained. The Device Master Record (DMR) is complete. Processes are validated via equipment qualification (installation and operational qualification), process qualification and product performance qualification.

#### 7.3.9 Design History File (DHF)

A DHF is maintained for all designs, with all records necessary to demonstrate that the design was developed according to the design plan, to established procedures and to applicable regulatory requirements. Where NDC does not have primary design responsibility, NDC will maintain a copy of the project Design History File index (table of contents) as well as copies of all design-related items generated by NDC.

### 7.4 Purchasing

NDC purchases supplies and subcontracted products/services from those that can satisfy quality, technical, and delivery requirements. Within the Scope, suppliers and subcontractors are evaluated to determine their capability, and approved suppliers are used to purchase items and services. Purchasing documents clearly describe the product or service to be purchased, including quality requirements. Purchasing documents are reviewed and approved prior to release.

#### 7.4.1 Purchasing process

The provisions of this section apply to materials, products, and services incorporated into NDC products, typically referred to as inventory items. It also applies to value-added services, key manufacturing supplies, and

services required by the quality management system. Common operating supplies and consumables use the same purchasing execution systems; however, controls are modified.

Suppliers are evaluated and approved based on their demonstrated or potential ability to meet quality, delivery, and price requirements. Evaluation and approval methods are defined.

Results of the evaluation aid in determining the approach to assuring the quality of a supplier's product; i.e., the level and intensity of inspection to be performed on receipt.

Approved Suppliers are documented in the purchasing system and the approved supplier list is managed in that system.

#### 7.4.2 Purchasing information

Requirements for purchased products are defined in the Purchase Order (PO) and referenced documents. Referenced documents must include the Revision Level, if applicable. The reviewer/approver of the PO is responsible for reviewing the adequacy of the data, such as:

- description of item/material/service purchased
- quality or performance requirements
- certification and other documentation requirements
- indication of Company requirements, such as calibration, inspection, etc.
- use of approved suppliers

The reviewer/approver signs the Purchase Order indicating the accomplishment of the above review.

Reviewer/approver status is established.

Suppliers are requested to enter into an agreement to notify the company of any process or material changes that may affect the quality of the company's product.

#### 7.4.3 Verification of purchased product

Within the scope, purchased product is inspected upon receipt to the extent necessary to verify conformance to requirements. Records of the inspection are kept.

Inspection and testing is planned and conducted when purchased materials and components are received. Inspections are conducted according to approved plans. Qualified individuals from any organization may perform inspections and record results. Inspections may utilize data prepared by others to make decisions when specified in the Inspection Plan. Qualified inspectors or those specifically delegated must close out all Inspection Plans. Records are made of inspections specified in the Inspection Plan.

For serious or repeated quality problems with a supplier, a Supplier Corrective Action Request (SCAR) is prepared and sent to the supplier for corrective action and response. Follow-ups are performed as required.

Verification at Subcontractor's Premises – When necessary or desirable to verify product at a subcontractor's facility, that requirement is cited in the Purchase Order.

Customer Verification of Subcontracted Product – Verification of subcontracted product by customers may be arranged on a case-by-case basis, and should be specified in the Purchase Order or contract.

## 7.5 Production and Service Provision

### 7.5.1 Control of production and service provision

Production operations that affect quality are planned and carried out under controlled conditions. Adequate processes and documented procedures are used. Work instructions are prepared to provide for uniform accomplishment of processes where the traveler cannot provide sufficient detail. Processing equipment is checked and maintained to provide consistent performance. Production areas are appropriately clean and suitable for the operation performed and the material processed.

Key processing equipment is evaluated prior to use / installation and/or during its lifetime to determine or change maintenance schedules. The engineer is responsible for identifying equipment to be included in the schedule, the frequency of maintenance or verification, and the acceptable operating tolerances. The Operations (Production) Manager is responsible for execution of the schedule and any required actions, and the collection of records. Records indicate the action performed, the date performed, who performed it, and any actions taken. The schedule is maintained by the Operations (Production) Manager. When equipment which has missed a maintenance due date is used for production, a nonconformance is generated. The NCR includes an investigation of the reason(s) that the equipment has not been maintained and a disposition for use of the equipment and any material that was produced on the equipment after the due date.

The operations group is responsible for producing and maintaining demand schedules for the manufacturing areas. This is accomplished through the coordination of sales activities with material availability and manufacturing capabilities. A backlog of deliverable orders is generated and reviewed. As a result of these reviews, manufacturing and inspection activities are coordinated and performed.

The traveler is a controlled document that defines the source material(s), the sequence of operations, processing instructions, and verification steps.

When processing instructions are lengthy (usually when they exceed three lines on a traveler), or an inspection/test procedure is complicated, a Work Instruction is prepared and available at the work site. The traveler or Inspection Plan references the Work Instruction at the appropriate step.

Workmanship standards are created as retained samples, photographs, or written descriptions. The preferred sample is the "worst acceptable" condition. Establishment of and changes to standards are performed as needed. The approval is on a tag or other document physically attached to the sample.

Inspection Plans are used to perform receiving, in-process and final inspections. Based on the result of the inspections, product is dispositioned.

The mode of delivery is as specified by the customer. Requirements are entered with the order and appear on the Packing Slip.

Servicing does not apply to NDC's products, as mentioned in the exclusion section.

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

Where characteristics cannot be checked after processing, processes are validated (qualified) and/or monitored to assure adequate results are obtained. Software that is used to make decisions in the manufacture or evaluation of product that directly affects product quality is validated. Software that is used to control manufacturing processes or perform calculations is verified to ensure it performs as intended.

When changes are made to a process, revalidation may be required. Revalidation procedures are documented in OP-9009-9, Process Improvement Control.

Validated equipment shall be identified after validation is complete. Such equipment shall be operated by trained personnel only.

#### 7.5.3 Identification and traceability

Products are identified by description and the lot number. Traceability from the lot number to precursor lot numbers and the source material is maintained.

The part and/or product description is assigned, and typically provides a description of the item and/or a link to the technical documentation. All product is identified to that description and a unique lot number through the use of tags or labels. Batches may be assigned within a lot. Devices and components are serialized when necessary or appropriate.

Assigned descriptions are recorded in the company system (Parts module). Lot numbers are assigned by the Inventory module in the company system for received and manufactured items. Production lots are made from the same source material and the same setup. Batch numbers may be established within a production lot as required to expedite or facilitate processing. The Lot History File (Device History Record for finished devices) contains all pertinent records of lot, batch, and serial number assignment.

The status of product is clearly identified to assure that only product of known conforming quality is used, installed, or shipped. The status of product is identified by use of labels or tags, the completion status of travelers and quality plans, or its presence in a labeled location.

#### 7.5.4 Customer property

Customer-supplied product is treated in the same manner as other received material or components. Verification is performed and traceability is maintained as required. Customer supplied product is clearly identified and segregated from similar, non-customer supplied material.

Customer supplied material is labeled and entered into the inventory system in a RESTRICTED status, indicating the ownership. Product provided for conversion (value-added processing) is maintained with the customer's identification until the conversion is complete.

Traceability is maintained to the material or product received from customers.

If there are discrepancies noted at any time, the customer is notified for disposition instructions.

#### 7.5.5 Preservation of product

The company operates in a clean industrial environment. Materials and products are managed to prevent damage and significant contamination during all stages of post-manufacturing.

Where special handling is required to prevent damage, precautions are taken on a case by case basis. Requirements are specified on specifications, travelers, packing slips, or other documents as appropriate.

Material and parts are stored in locations tracked by the company system. All material in storage is clearly identified as to description and inspection status.

Standard packaging procedures are described in Work Instructions or Travelers. Unique, customer-specific requirements are entered with the order and appear on the Packing Slip at time of shipment.

Generally, preservation, is not applicable or an issue due to the nature of the material.

### 7.6 Control of monitoring and measuring devices

All inspection, measuring, and test equipment that affects product quality is controlled, calibrated, and maintained. Personally owned equipment within that scope is included. Calibration is traceable to the NIST or appropriate physical standard. All equipment is labeled as to its status in the calibration system. Equipment is selected to support the accuracy required by the product drawing or specification. Test equipment software is controlled.

Inspection, measuring, and test equipment is selected to provide the appropriate level of accuracy and precision required.

A master list is maintained in the company database of all equipment in the calibration system. Items excluded from the calibration system are recorded and a rationale for that exclusion is recorded. Items are labeled with the corresponding calibration status.

Items that require maintenance are listed on the Preventive Maintenance Database, which shows the identification, location, tasks to be performed, and the maintenance cycle. The database reflects the accomplishment of the maintenance; detailed records may be kept at the location of the maintained item.

Calibration services may be performed internally by controlled procedure or through outside services in compliance to Purchase Specifications.

#### 7.7 References for this section

OP-9003,	Contract Review
OP-9003-1,	Order Entry
OP-9003-2,	Specification Review
OP-9004,	Design Control
OP-9004-1,	Process FMEA
OP-9004-7,	Laboratory Notebook
OP-9004-9,	Manufacturing Readiness Review
OP-9004-10,	Manufacturing Quality Plan
OP-9004-11,	Design Verification & Design Validation Requirements for NDC-Designated Medical Devices and Components
OP-9004-13,	Product Risk Analysis
OP-9004-14,	Design Inputs and Design Outputs
OP-9005-5,	Customer Document Control
OP-9006,	Purchasing
OP-9006-1,	Supplier Management
OP-9008,	Product Identification & Traceability
OP-9009,	Process Control
OP-9009-1,	Preventive Maintenance
OP-9009-2,	Manufacturing Process Validation
OP-9009-4,	Manufacturing Tooling Qualification
OP-9009-9,	Process Improvement Control
OP-9010,	Inspection and Testing
OP-9010-1,	Receiving Inspection
OP-9011,	Calibration - Inspection, Measuring and Test Equipment
OP-9012,	Inspection and Test Status
OP-9014-2,	Complaints
OP-9015,	Handling, Storage, Packaging, Preservation, and Delivery
OP-9015-1,	Material Management
OP-9015-3,	Receiving



## 8 Measurement, Analysis and Improvement

### 8.1 General

To ensure product conformity to specification, inspection and testing is planned and conducted when purchased materials and components are received, at key stages of processing, and before release of product. Inspections are conducted according to approved inspection plans. Records are made of inspections specified in the Inspection Plan.

Customer satisfaction is monitored and measured using several sources. The information from these sources are reviewed at the management review meetings.

Internal Audits are conducted to ensure conformity and effectiveness of the quality management system. The results of such audits are reviewed at the management review meetings.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate for measurement, analysis and improvement.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

### 8.2 Monitoring and measurement

#### 8.2.1 Customer Satisfaction

Customer satisfaction is monitored and measured primarily through customer complaints, returned goods and delivery information. The information from these sources is reviewed at the management review meetings. Other indicators or sources for customer satisfaction used at NDC include sales volume tracking, customer audits, customer provided supplier ratings, etc.

##### 8.2.1.1 Customer Complaint Handling

Procedures are established to manage the resolution of complaints received on all NDC products. Where a product is included in a finished medical device sold by medical device manufacturing companies, the company will respond to requests and inquiries in support of the complaint investigation led by the seller. Such requests are entered into the complaint system for tracking, and into the Corrective and Preventive Action system if action is required. A complaint may also be issued when a corrective action request is initiated by a customer.

US FDA Medical Device Reporting requirements are coordinated by the medical device manufacturer. EU Vigilance Reporting is coordinated by the medical device manufacturer.

Customer complaints are examined for systemic issues during Management Review and when appropriate, Management issues Corrective Actions to address identified issues.

#### 8.2.1.2 Returned Goods

Customer satisfaction is also tracked through the number of returns from the customer. Returns to the company are authorized by a Return Authorization (RA) number. The percent returns and the dollar amount of returns vs. shipments are tracked and trended. Target goals have been set for both indicators. The reason for the return is also recorded. The data is reviewed at management review meetings and appropriate actions taken as necessary.

#### 8.2.1.3 Delivery

The mode of delivery of product is specified by the customer. The delivery requirements are entered with the order and appear on the Packing Slip. Delivery information is tracked and trended. Target goals have been set.

Delivery indicators that are tracked and trended are % on-time delivery and average days late. The data is reviewed at management review meetings and appropriate actions taken as necessary.

#### 8.2.1.4 Other Customer Satisfaction Indicators

Other indicators or sources used to monitor customer satisfaction are:

- Sales forecast and volume reviewed periodically to determine if sales plan is being met or if adjustments are necessary based on specific customer feedback.
- Customer Audits performed by some customers will be documented at the customer's discretion. These customer audit results are reviewed by management and retained.
- Customer supplier ratings provided by some customers

### 8.2.2 Internal Audit

Audits of the quality system are performed on a scheduled basis to measure compliance to applicable standards and the effectiveness of the quality system. Qualified employees or outside consultants perform the audits. The auditor must have no direct responsibility for the area audited. Audit results are subject to Management Review.

#### 8.2.2.1 Audit Schedules

All elements of the quality system are audited on an annual basis. A tolerance of plus or minus one calendar quarter is permitted.

#### 8.2.2.2 Audit Plans

Checklists are created to allow systematic and efficient auditing. Known issues and the history of the area or element audited may be used to develop areas of concentration.

#### 8.2.2.3 Audit Results

Each audit generates a report and requests for corrective action, if necessary. Audit corrective actions are logged and managed according to the Corrective and Preventive Action system; however, the records of the Internal Audits are considered company-confidential.

#### 8.2.2.4 Follow-up

Where corrective action is required, it is verified by the original auditor or another qualified individual. The adequacy of follow-up is audited during subsequent audits and/or during the annual audit of the internal audit system. Records of the follow-up are kept.

### 8.2.3 Monitoring and Measurement of Processes

The key quality management system processes at NDC have been identified as:

- Supplier Management
- Process Control
- Handling, Storage, Packaging and Delivery
- Resources (Personnel, Facilities, Equipment)
- Document Control
- Regulatory Requirements

The following methods are in place to measure and monitor the above processes:

- Internal Quality Audits
- Other internal audits (workstation practices audit, line clearance audits, etc)
- Customer Satisfaction (Complaints, Delivery and Returns)
- Product Acceptance/ non-conformance
- Management Review process

The intended purpose of the above key processes are quantified by output of the processes, such as conformance to product specifications, yields, etc.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

Procedures are developed and used to assure uniform application of the techniques selected.

Processes are evaluated to determine the statistical capability, and improvements and/or the application of SPC are utilized to provide capable processes. DOE techniques are applied to optimize processes and to improve them where capability does not meet requirements. Sampling plans are selected according to results of risk analysis and other analyses of product and process. Sampling plans are reviewed as needed, based upon frequency of nonconformances and other feedback information to assure their adequacy.

#### 8.2.4 Monitoring and Measurement of Product

##### 8.2.4.1 Receiving Inspection

Material intended for use in final product (inventory item) is subject to inspection according to an Inspection Plan. Urgently required material may be pre-released to production. In that case, the traveler for the job is annotated "PRE-RELEASED MATERIAL" or similar, and the acceptability of the material is verified before the traveler is completed and the product is released.

##### 8.2.4.2 Inprocess Inspection

Inprocess inspections are performed as required at specified points on the Traveler or as required by a Work Instruction. These may be performed by qualified production or inspection personnel. Records are maintained.

##### 8.2.4.3 Final Inspection

Final inspections are performed to confirm that all production operations are complete and that product meets requirements. The final inspections are performed before the product is shipped or placed in finished goods inventory. Verification of the acceptability of pre-released material is performed before final acceptance. Quality Assurance personnel, or others specifically delegated, must close out the inspection by signing the Inspection Plan indicating the inspection is complete and all required actions accomplished.

#### 8.2.4.4 First Article Inspection

First Article Inspections are performed at the discretion of the Production Manager unless the Traveler or other specifying document specifically requires the performance of the First Article.

#### 8.2.4.5 Inspection and Test Records

Records are made of inspections specified in the Inspection Plan.

### 8.3 Control of nonconforming product

To prevent unintended use or installation, nonconforming product is clearly identified by labeling of the product and/or its placement in an area specifically reserved for nonconforming material. Responsibility for dispositioning is defined. Use-As-Is dispositions for specified requirements require the approval of the customer and the VP QA/RA. Use-As-Is dispositions typically require the establishment or revision of specifications, workmanship standards, or other requirements documents.

#### 8.3.1 Physical Controls

“REJECTED” or “SCRAP” labels/tags are used to identify nonconforming material. That material is labeled and/or placed in a location reserved for nonconforming or suspect material. “HOLD” or “QC HOLD” labels are used for material that has been found to be discrepant during inspections but not yet dispositioned.

#### 8.3.2 Review And Disposition

Nonconforming material is documented on a Nonconformance Report (NCR). Each document requires review, evaluation, and disposition. Where Work Instructions contain specific nonconformance identification and disposition actions, the material may be rejected, properly identified (labeled "REJECTED") and accounted for on the Traveler by the operator without further approvals.

#### 8.3.3 Waivers and Deviations

Where nonconforming material is to be offered to a customer, a waiver or deviation (customer concession) must be obtained from the customer's authorized representative prior to shipment. Where a written confirmation is unavailable, the documentation must show the name of the customer representative granting the verbal waiver, and the dated signature of the company representative documenting the verbal communication. All waivers and deviations are limited by time, quantity, or lot number.

#### 8.3.4 Referral for Corrective and Preventive Action

Some nonconformances may dictate the generation of a formal Corrective Action Request. Corrective and preventive actions process is described in OP-9014.

## 8.4 Analysis of Data

NDC has determined the appropriate data to be collected to demonstrate the suitability and effectiveness of the quality management system and determine where improvement is needed. This data consists of Internal Audits results, Customer Satisfaction information (customer complaints, on time delivery, and returns), Non-conformance and product yields.

The monitoring and measurement methods for key processes are the input to Management Review. The continuing suitability of these processes are confirmed at the Management Review meetings and documented in the meeting notes.

The data analysis and review may also result in generating and corrective and preventive actions, identification of improvements, supplier information, trends and determining the suitability and effectiveness of the QMS based on Quality policies and objectives.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

## 8.5 Improvement

### 8.5.1 Continual Improvement

Management with executive responsibility (executive management) is responsible for establishing, implementing, and continuously improving the quality system.

Executive management, and others as required, formally reviews the quality system for compliance and effectiveness at least quarterly. Results and actions taken are documented.

Procedure for advisory notices and regulatory notification is not required, as NDC is currently not manufacturing finished medical devices.

Customer complaints are recorded and investigated. If a corrective action/preventive action is not issued for a device complaint, the reason should be recorded. Results of all investigations must be documented.

### 8.5.2 Corrective Action

Corrective action is recognized as a key element in the continued improvement in quality. Corrective Actions are taken to eliminate the causes of an existing nonconformance, defect, or other undesirable situation in order to prevent recurrence. Corrective actions are put into place once something has been identified as having gone wrong. Corrective action definition and details are documented in OP-9014, Corrective and preventative action. The management team assures adequate resources are available to identify and implement corrective and preventive actions.

### 8.5.3 Preventive Action

Preventative action is recognized as a key element in the continued improvement in quality. Preventive Actions are taken to eliminate the cause of a potential nonconformance, defect, or undesirable situation to prevent occurrence. The degree of preventative action taken should be dependent upon and related to the risk, size, and nature of the problem and its effect(s) on product quality. Preventive actions are more proactive and are put in place once something has been identified as having the possibility of going wrong.. Preventive action definition and details are documented in OP-9014, Corrective and preventative action. The management team assures adequate resources are available to identify and implement preventive actions. .

### 8.6 References for this section

OP-9001, Management Responsibility  
OP-9009 series, Process control  
OP-9010-1, Receiving Inspection  
OP-9010-2, In-Process Inspection  
OP-9010-3, Final Inspection  
OP-9013, Nonconforming Material  
OP-9014, Corrective and Preventive Actions  
OP-9014-2, Complaints  
OP-9015, Handling Storage, Packaging and Delivery  
OP-9015-3, Receiving  
OP-9017, Internal Audits  
OP-9020, Statistical Techniques

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