Integrity Systems Precision

SURGICAL & AEROSPACE MACHINING

Quality Manual

Integrity Systems
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Contents

Introduction

Integrity Systems developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Integrity Systems meets the requirements of the international standard **ISO 13485:2016**. This system addresses the key processes in the production of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of **ISO 13485:2016.** Each section begins with a policy statement expressing Integrity Systems' obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

Owner: _____

Quality Manual Distribution

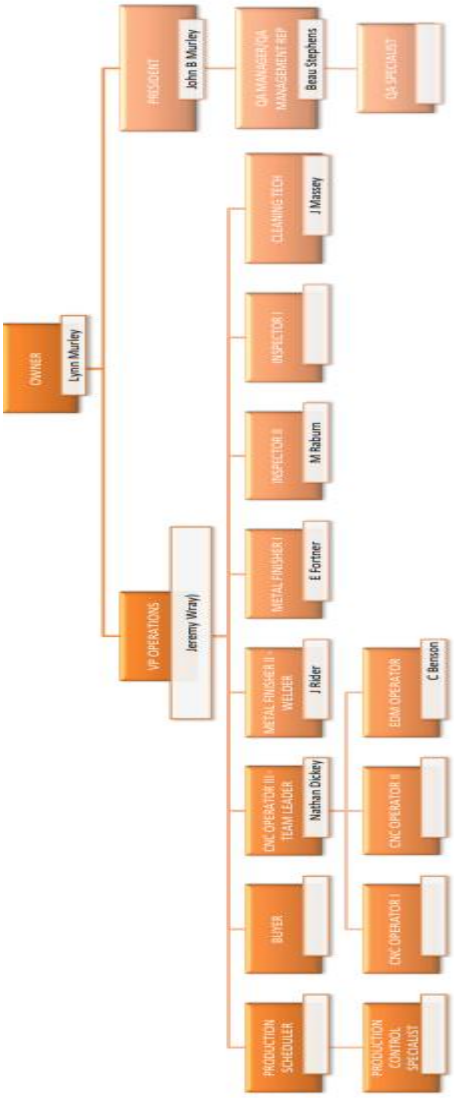
The Quality Manual shall be distributed to the following:

The Quality Manual is not distributed in printed copies. Printed copies are not controlled.

Controlled copies of the Quality Manual are only viewable over the Integrity Systems Network. It can be viewed by any employee on any computer with domain access.

All employees are instructed on how to view the Quality Manual and/or related Quality Procedures and Work Instructions.

Integrity Systems Organizational Chart:



Section 1: Scope

1.1 General

This quality manual outlines the policies, procedures and requirements of the Quality Management System at Integrity Systems. The system is structured to comply with the conditions set forth in the International Standard ISO 13485:2016 and Integrity Systems' customer Quality Agreements.

1.2 Application

Integrity Systems has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

Exclusions - Sections of the ISO 13485 Standard which do not apply to Integrity Systems are as follows:

a) **Clause 7.3** – Design and Development (Reason: No design or development activities at Integrity Systems)
b) **Section 7.5.3** - Installation activities (Reason: Applicable to equipment)
c) **Section 7.5.4** - Service activities (Reason: Applicable to equipment)
d) **Section 7.5.5** - Particular requirements for sterile medical devices (Reason: No sterile products)
e) **Section 7.5.7** - Particular requirements for sterile medical devices (Reason: No sterile products)

1.3 Applicable Standards & Regulations

1.3.1 ISO 13485:2016 – Medical devices – Quality Management Systems – Requirements for regulatory purposes,

1.3.2 FDA 21 CFR 820 - Quality System Regulation (QSR)

Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

a) ISO 13485:2016 - Medical devices, Quality management systems - Requirements for regulatory purposes

b) ISO 9000:2015, Quality Management Systems – Fundamentals & Vocabulary.

c) ISO 9004:2000, Quality Management Systems – Guidelines for performance Improvements

Section 3: Definitions

3.0 Quality Management System Definitions

3.1 Advisory Notice – notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in

- use of a medical device,

- modification of a medical device,

- return of the medical device to the organization that supplied it,

- destruction of a medical device.

Note Issue of an advisory notice can be required to comply with applicable regulatory requirements

3.2 Authorized Representative – natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

3.3 Clinical Evaluation – assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

3.4 Complaint - written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices

3.5 Distributor – natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

3.6 Implantable medical device - medical device which can only be removed by medical or surgical intervention and which is intended to:

- be totally or partially introduced into the human body or a natural orifice, or

- replace an epithelial surface or the surface of the eye, and

- remain after the procedure for at least 30 days

NOTE: This definition of implantable medical device includes active implantable medical device.

3.7 Importer – natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to me marketed.

3.8 Labelling – label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

3.9 Lifecycle – all phases of a medical device, from the initial conception to final decommissioning and disposal

3.10 Manufacturer – natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

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

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

- investigation, replacement, modification, or support of the anatomy or of a physiological process,

- supporting or sustaining life,

- control of conception,

- disinfection of medical devices,

- providing information by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by

pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

NOTE Products which may be considered to be medical devices in some jurisdictions but not in others include: disinfection substances, aids for persons with disabilities, devices incorporating animal and/or human tissues, devices for in vitro fertilization or assisted reproduction technologies.

3.12 Medical Device Family – group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function

3.13 Performance Evaluation – assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use

3.14 Post-Market – systematic process to collect and analyze experience gained from medical devices that have been placed on the market

3.15 Product - result of a process

3.16 Purchased Product – product provided by a party outside the organization's quality management system

3.17 Risk – combination of the probability of occurrence of harm and the severity of that harm

3.18 Risk Management – systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

3.19 Sterile Barrier System – minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

3.20 Sterile medical device - medical device intended to meet the requirements for sterility. NOTE the requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

3.21 Definitions Specific to Integrity Systems

Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.

Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.

Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable

Statutory Requirements - NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.

Section 4

Quality Management System

4.1 General requirements

4.1.1 Integrity Systems has documented a quality management system and maintains its effectiveness in accordance the requirements of the International Standard and applicable regulatory requirements.

The organization has established, implemented and maintains any requirement, procedure, activity or arrangement required to be documented by the International Standard or applicable regulatory requirements.

The organization has documented the role(s) undertaken by the organization under the applicable regulatory requirements.

4.1.2 Integrity Systems has:

a) Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual

b) Applied a risk based approach to the control of the appropriate process needed for the QMS

c) Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram

4.1.3 Integrity Systems has:

a) Determined criteria and methods needed to ensure that the operation and control of the processes are effective

b) Ensured the availability of resources and information necessary to achieve planned results and continual improvement of these processes

c) Implement actions necessary to achieve planned results and maintain the effectiveness of these processes

d) Established systems to monitor, measure as appropriate, and analyze these processes

e) Established and maintained records needed to demonstrate conformance to the International Standard and compliance with applicable regulatory requirements

4.1.4 Integrity Systems has implemented processes to manage these QMS processes and to evaluate any changes to these processes.

a) Evaluated any changes for their impact on the QMS

b) Evaluated any changes for their impact on the medical devices produced under this QMS

c) Controlled in accordance with the requirements of the International Standard and applicable regulatory requirements

4.1.5 Integrity Systems will ensure control over outsourced processes that affects product conformity to requirements. Controls shall be proportionate to the risk and the ability of the external party to meet the requirements and will include written quality agreements

4.1.6 Integrity Systems procedure Validation Software (P-416) documents the procedures for the validation of the application of software used in the QMS. Software is validated prior to initial use and, as appropriate, after changes to the software or application. The specific approach and activities associated with the software validation and revalidation will be proportionate to the risk associated with the use of the software.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

a) A documented Quality Policy and documented Quality Objectives

b) This Quality Manual

c) Documented Procedures and records

d) Documents, including records, identified as needed for the effective planning, operation and control of our processes, and

e) Any other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

This Quality Manual has been prepared to describe Integrity Systems' QMS.

a) The scope and permissible exclusions of the QMS are described in section one of this manual.

b) Each section of the manual references documented QMS procedures relating to the requirements outlined in that section.

c) The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

The Quality Management System used the following levels of documentation:

a) Quality Manual

b) Procedures – reference work instructions applicable to the procedure and forms and records required for the procedure

c) Work Instructions – reference forms and records required for the work instruction

d) Records

4.2.3 Medical device file

For each medical device type or medical device family, Integrity Systems shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

Integrity Systems does not design or develop medical devices however, the requirements as defined by our customer are reviewed and documented as part of the contract review process and maintained through the Device History Records.

The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any

instructions for use performed by OEM

b) specifications for product; as provided by the customer

c) specifications or procedures for

manufacturing (included in the DHR),

packaging (Integrity Systems does not perform product packaging),

storage (Integrity Systems procedure P-755 Preservation of Property),

handling (Integrity Systems procedure P-755 Preservation of Property) and distribution (Integrity Systems does not distribute product)

d) procedures for measuring and monitoring; Control Plans as required by the customer, Integrity Systems procedure P-825 Monitoring, Measuring and Analysis of Product and Realization Processes, and Inspection Procedures maintained in DHR

e) as appropriate, requirements for installation; Integrity Systems does not perform installations

f) as appropriate, procedures for servicing. Integrity Systems does not perform servicing activities

4.2.4 Control of documents

All of the QMS documents are controlled according to the Document Control Procedure (P-423). This procedure defines the process for:

a) Review and approval of documents for adequacy prior to issue,

b) Reviewing and updating as necessary and re-approving documents

c) Ensuring that changes and current revision status of and changes to documents are identified

d) Ensuring that relevant versions of applicable documents are available at points of use

e) Ensuring that documents remain legible and readily identifiable

f) Ensuring that documents of external origin, determined by the organization to be necessary for the planning and operation of the QMS, are identified and their distribution controlled

g) Preventing deterioration or loss of documents

h) Preventing the unintended use of obsolete documents and apply suitable identification to them

i) Changes to documents are reviewed and approved by same function that approved the original document, or by another designated function with access to pertinent background information

j) The master list defines the period of time that at least one copy of obsolete controlled documents is retained. This period is sufficient to ensure that documents used for manufacture or test of medical devices are available for at least the lifetime of the device, and not less than the retention period of records or specifications of regulatory requirements

4.2.5 Control of records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure (P-425). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

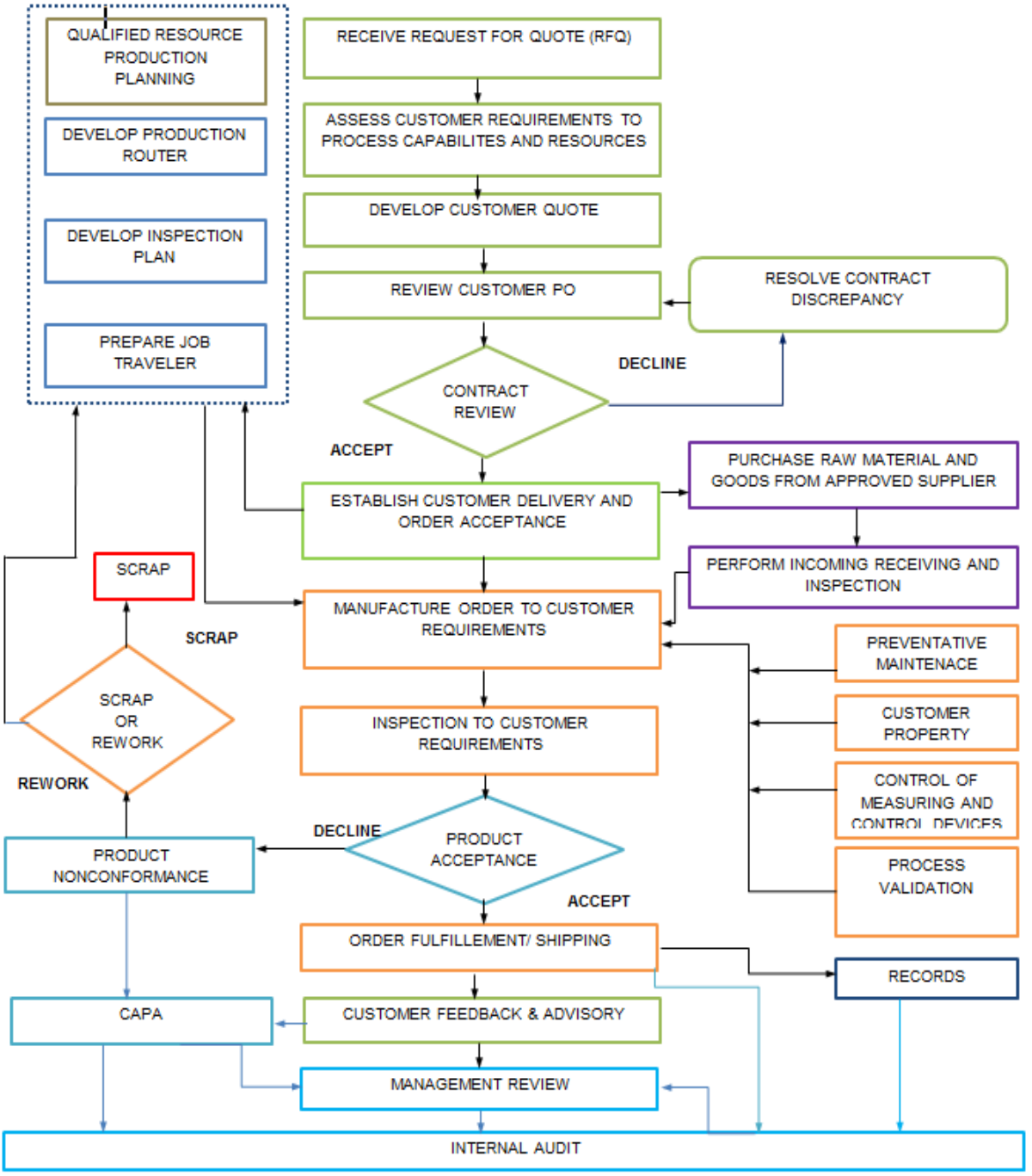
Quality records are retained for a period of time at least equivalent to the lifetime of the medical device and not less than two years from the date of product release or specifications of relevant regulatory requirements. The standard practice at Integrity Systems is to retain quality records forever.

Related Procedures

P-423 Document Control

P-425 Control of Quality Records

INTEGRITY SYSTEMS MANUFACTURING PROCESS FLOW AND INTERACTION REV B



Section 5

Management Responsibility

5.1 Management commitment

Management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

Management provides evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by:

a) Communicating the importance of meeting customer, statutory, and regulatory requirements.

b) Establishing quality objectives

c) Establishing the quality policy.

d) Conducting management reviews.

e) Ensuring the availability of resources.

5.2 Customer focus

Integrity Systems strives to identify current and future customer needs and to meet customer requirements.

Management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (P-720).

5.3 Quality policy

Management ensures that the quality policy includes a commitment to comply with requirements and to maintain the effectiveness of the Quality Management System. The Quality Policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented on QP-IS.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established at relevant functions and levels in Integrity Systems in order to support our organization's efforts in achieving our Quality Policy.

Quality objectives are consistent with the Quality Policy. They are measurable and reviewed against performance goals at each management review meeting.

Quality Objectives are documented on Integrity Form 0081-IS, Quality Objectives Matrix.

5.4.2 Quality management system planning

Integrity Systems management ensures:

a) The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 13485 standard.

b) Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, authority and communication

Integrity Systems procedure, Management Responsibility (P-550) describes the Management Responsibilities for the Quality Management System

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of all personnel who manage, perform and verify work affecting quality. Management ensures that each position has the independence and authority to perform these tasks. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by Management for adequacy. These documents are available throughout the organization to communicate responsibilities and authorities. An organizational chart is located in this Quality Manual.

5.5.2 Management representative

The Quality Assurance Manager has been appointed by Management as management representative. As management representative, they have the following responsibility and authority:

a) Ensure that processes needed for the quality management system are documented.

b) Report to Management on the effectiveness of the quality management system, and note needed improvements.

c) Promote awareness of customer requirements throughout the organization.

d) Ensuring the promotion of awareness of applicable regulatory requirements and QMS requirements throughout the organization.

e) Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

5.6 Management review

5.6.1 General

Management reviews of the QMS are held and documented according to the Management Review Procedure (P-560). These review meetings are held annually at a minimum. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

a) feedback

b) Customer feedback (complaint handling)

c) Reporting to regulatory authorities

d) Results of audits

e) Monitoring and measurement of Process performance

f) Monitoring and measurement of product conformity

g) Status of corrective actions

h) Status of preventive actions

i) Follow-up actions from previous management reviews

j) Planned changes that could affect the quality management system

k) Recommendations for improvement

l) Applicable new or revised regulatory requirements.

5.6.3 Review output

The output from management review shall be recorded and include the input reviewed and any decisions and actions related to:

a) Improvement needed to maintain the suitability, adequacy, and effectiveness of the Quality Management System and its processes

b) Improvement of product related to customer requirements

c) Changes needed to respond to applicable new or revised regulatory requirements

d) Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Related Procedures:

P-500 Management Responsibility

P-560 Management Review

P-720 Customer Related Processes

P-710 Quality Planning

Section 6

Resource Management

6.1 Provision of resources

Integrity Systems has implemented a Quality Management System that complies with the ISO 13485:2016 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. Management determines and provides necessary resources to maintain effectiveness of the quality system, and to meet applicable regulatory and customer requirements.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human Resources maintains records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure. (P-622)

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Integrity Systems has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment (both hardware and software) and supporting services. As new infrastructure requirements arise, they will be documented in quality plans.

Existing infrastructure is maintained to ensure product conformity. Requirements for maintenance activities, including their frequency are documented when such activities or lack thereof can affect product quality.

Records of maintenance are maintained.

The Infrastructure Maintenance Table documents requirements and where records are kept. (Form 0089-IS)

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

a) If contact between personnel and the product or the work environment could adversely affect product quality, Integrity Systems establishes documented requirements for heath, cleanliness and clothing. Requirements are included in documented procedures or work instructions.

b) If conditions in the work environment can adversely affect product quality, Integrity Systems establishes documented requirements for work environment conditions, and documented procedures or work instructions to monitor and control these conditions. Requirements are included in documented procedures or work instructions.

c) All personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person according to Procedure P-622, Competence, Awareness and Training.

6.4.2 Contamination Control

If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

Related Documents

P-622 Competence, Awareness and Training

P-640 Work Environment

0089-IS Infrastructure Maintenance Table

Section 7

Product Realization

7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning takes place according to the Planning of Product Realization procedure (P-710). During this planning, management or assigned personnel identify:

a) The quality objectives and requirements for the product,

b) Processes, documentation and resources (infrastructure) and work environment required

c) Verification, validation, monitoring, inspection and test requirements, handling, storage, distribution and traceability activities and

Criteria for product acceptance

d) Records needed to provide evidence that the realization process and resulting product meet requirements

The output of quality planning includes documented quality plans. Quality plans at Integrity Systems may exist in one or more of the following formats:

a) Part Travelers

b) Inspection Procedures

c) Setup Procedures

d) Established Bills of Materials

e) Control Plans

f) Processes

g) Quality Procedures

Risk management requirements are documented in P-711, Risk Management. Records arising from risk management are maintained.

7.2 Customer-related processes

7.2.1 Determination of requirements related to product

Integrity Systems determines customer requirements before acceptance of an order. Customer requirements include those:

Requested by the customer

a) Required for delivery and post-delivery activities

b) Not stated by the customer but necessary for specified use or known and intended use

c) Applicable requirements related to the product

d) Additional requirements determined by Integrity Systems

Customer requirements are determined according to the Customer Related Processes Procedure. (P-720)

7.2.2 Review of requirements related to product

Integrity Systems has a procedure in place for the review of requirements related to the product (P-720). The review is conducted before the order is accepted. This procedure ensures that:

a) Product requirements are defined and documented.

b) Contract or order requirements differing from those previously expressed are resolved

c) Integrity Systems has the ability to meet the defined requirements

d) Records are maintained showing the results of the review and any actions arising from the review

e) Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance

f) When product requirements are changed, Integrity Systems communicates changes to relevant personnel and amends relevant documents

7.2.3 Communication

Integrity Systems has implemented an effective procedure (P-720) for communicating with customers in relation to:

a) Product Information

b) Enquiries, contracts and order handling, including amendments

c) Customer Feedback, including complaints

d) Advisory Notices - Procedure P-851, Product Recall and Advisory Notices has been implemented for effective communication with customers in the event of an Advisory Notice

7.3 Design and Development

Integrity Systems takes exclusion to Clause 7.3.

Reason: No design or development activities at Integrity Systems. (Reference Section 1.2 (a) of this Quality Manual.

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (P-740) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Procedure P-741 documents the evaluation, selection, monitoring and re-evaluation of Suppliers based on Supplier Class where they are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation, monitoring, re-evaluation, and any necessary actions are maintained as quality records.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including as appropriate:

a) Product Specifications

b) Requirements for product acceptance, procedures, processes and equipment

c) Requirements for qualification of personnel

d) Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

Integrity Systems maintains relevant purchasing information, documents and records, to the extent required for traceability.

7.4.3 Verification of purchased product

The Purchasing procedure (P-740) describes the process used to verify that purchased product meets specified purchase requirements. If Integrity Systems or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Records of the verification are maintained.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Integrity Systems plans and carries out production and service provision under controlled conditions. These conditions are defined in procedure Control of Production and Service Provision (P-750)

Controlled conditions include:

a) The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary for the control of production

b) The use of suitable, qualified, and maintained equipment

c) The implementation of monitoring and measurement of process parameters and product characteristics

d) The availability and use of monitoring and measuring equipment

e) The implementation of defined operations for labeling and packaging

f) The implementation of product release, delivery, and post-delivery activities

Integrity Systems has established and maintains a record (refer to 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record is verified and approved.

NOTE: A batch can be a single medical device.

7.5.2 Cleanliness of product

Integrity Systems has established documented requirements for cleanliness of product or contamination control of product if :

a) Product is cleaned by Integrity Systems prior to sterilization or its use

b) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use

c) Product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use

d) Product is supplied to be used non-sterile and its cleanliness is of significance in use

e) Process agents are to be removed from product during manufacture

7.5.3 Installation activities

Integrity Systems takes exclusion to 7.5.3

Reason – Applicable to equipment

Reference Section 1.2 (b) of this Quality Manual.

7.5.4 Servicing activities

Integrity Systems takes exclusion to 7.5.4

Reason – Applicable to equipment

Reference Section 1.2 (c) of this Quality Manual.

7.5.5 Particular requirements for sterile medical devices

Integrity Systems takes exclusion to 7.5.5

Reason – No sterile products

Reference Section 1.2 (d) of this Quality Manual.

7.5.6 Validation of processes for production and service provision

Integrity Systems procedure Validation of Processes for Product Realization (P-756) describes the validation activities associated with any processes for production and service provision where the resulting output cannot be or is not

verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of these processes to achieve planned results consistently.

Integrity Systems documents procedures for validation of processes, including:

a) defined criteria for review and approval of the processes;

b) equipment qualification and qualification of personnel;

c) use of specific methods, procedures and acceptance criteria;

d) as appropriate, statistical techniques with rationale for sample sizes; Procedure P-756.1 Process Failure Mode Effects and Analysis identifies and ranks failures. Procedure P-756.2 Sampling Plan for Process Validation describes the sample sizes and rationale behind them.

e) requirements for records (see 4.2.5);

f) revalidation, including criteria for revalidation;

g) approval of changes to the processes.

Integrity Systems procedure Document Control (P-423) documents the procedure to be used to make changes to processes. Changes to Travelers, Inspection Procedures, CNC Programs, Work Instructions and Procedures are initiated and approved through E2 software. Any training requirements are tracked through Training Manager software.

Integrity Systems procedure Validation – Software (P-416) documents procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation are maintained (see 4.2.4 and 4.2.5).

7.5.7 Particular requirements for sterile medical devices

Integrity Systems takes exclusion to 7.5.7

Reason – No sterile products

Reference Section 1.2 (e) of this Quality Manual.

7.5.8 Identification

Integrity Systems identifies the product by suitable means throughout product realization, and follows documented procedures for such product identification.

The identification of product status is maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

Integrity Systems identifies the product throughout product realization according to the Identification and Traceability procedure (P-758). Product is identified with respect to monitoring and measurement requirements.

Integrity Systems controls and records the unique identification of the product where ever traceability is a specified requirement

Integrity Systems has established a documented procedure (P-758) to ensure that medical devices returned to Integrity Systems are identified and distinguished from conforming product.

7.5.9 Traceability

7.5.9.1 General

Integrity Systems has established documented procedure, Identification and Traceability (P-758) for traceability that defines the extent of product traceability and the records required.

7.5.9.2 Particular requirements for implantable medical devices

In defining the records required for traceability, Integrity Systems includes records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. Integrity Systems requires that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection.

Records of the name and address of the shipping package consignee are maintained.

7.5.10 Customer property

Integrity Systems exercises care with customer property while it is under Integrity Systems' control or being used. A procedure (P-754) outlines the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records are maintained.

7.5.11 Preservation of product

Integrity Systems follows documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.

This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Documented procedures and work instructions are used for the control of product with a limited shelf-life or requiring special storage conditions. Special storage conditions are controlled and recorded.

Integrity Systems preserves the conformity of product during internal processing and delivery to the intended destination per procedure (P-755). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of monitoring and measuring equipment

Integrity Systems has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. A documented procedure (P-760) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Integrity Systems will establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards

b) Adjusted or re-adjusted as necessary. Any such adjustments will be recorded

c) Identified to enable the calibration status to be determined

d) Safeguarded from adjustments that would invalidate the measurement result

e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, the validity of the previous measuring results is assessed and recorded when the equipment is found not to conform to requirements. Integrity Systems takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Related Documents

P-710 Planning of Product Realization Processes

P-711 Risk Management

P-720 Customer Related Processes

P-740 Purchasing

P-741 Supplier Management

P-750 Control of Production and Service Provision

P-756 Validation of Processes for Product Realization

P-758 Identification and Traceability

P-754 Customer Property

P-755 Preservation of Property

P-760 Control of Monitoring and Measuring Devices

P-851 Product Recall and Advisory Notices

Section 8

Measurement, Analysis and Improvement

8.1 General

Integrity Systems plans and implements the monitoring, measurement, analysis and improvement processes as needed

a) demonstrate conformity of product;

b) ensure conformity of the quality management system;

c) maintain the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of appropriate methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, Integrity Systems monitors and gathers information relating to whether customer requirements have been met. The method for obtaining and using this information is identified and documented in the Customer Related Processes (P-720) and the Management Responsibility (P-500) procedures.

Integrity Systems has a documented Post Production Feedback (P-821) procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes. Where national or regional regulations require Integrity Systems to gain experience from the post-production phase, the review of this experience forms part of the feedback system according to P-821.

8.2.2 Complaint handling

Integrity Systems has defined the process by which complaints will be handled in procedure Complaint Handling (P-822) in order to accomplish timely complaint handling

in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for:

a) receiving and recording information;

b) evaluating information to determine if the feedback constitutes a complaint;

c) investigating complaints;

d) determining the need to report the information to the appropriate regulatory authorities;

e) handling of complaint-related product;

f) determining the need to initiate corrections or corrective actions.

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

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

Complaint handling records shall be maintained (see 4.2.5).

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, procedure, MDR Reporting (P-823) defines the process for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.5).

8.2.4 Internal Audit

Integrity Systems conducts internal audits at planned intervals to determine whether the quality management system:

a) Conforms to the planned and documented arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by Integrity Systems

b) Is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, interval, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (P-824).

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.5 Monitoring and measurement of processes

Integrity Systems applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (P-825) and Management Responsibility procedures (P-500).

8.2.6 Monitoring and measurement of product

Integrity Systems monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements and the documented procedure, Monitoring and Measuring of Product and Realization Processes P-825

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery do not proceed until the planned arrangements have been satisfactorily completed.

Integrity Systems records the identity of personnel performing any inspection or testing for implantable medical devices.

8.3 Control of Nonconforming Product

8.3.1 General

Integrity Systems ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (P-830).

The evaluation of nonconformity includes a determination of the need for an investigation. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation of any investigation and the rationale for decisions are documented and maintained

8.3.2 Actions in response to nonconforming product detected before delivery

Integrity Systems reviews the nonconformity and determines whether to take action to eliminate or correct the nonconformity, scrap the product and remove to a quarantined area, or request a concession from the customer.

Integrity Systems ensures that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession are maintained.

8.3.3 Actions in response to nonconforming product detected after delivery

If a nonconformity is detected after delivery, Integrity Systems notifies the customer of the nonconformity. Actions taken in response to the nonconformity are documented and maintained.

8.3.4 Rework

If product needs to be reworked (one or more times), Integrity Systems documents the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product is made and documented.

Reworked product shall be verified to ensure it meets all applicable acceptance criteria and regulatory requirements. Records of all rework are maintained.

8.4 Analysis of Data

Integrity Systems procedure Statistical Techniques describes the procedures to determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.

The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (P-500). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum input from:

a) Feedback

b) Conformance to product requirements

c) Characteristics and trends of processes and products including opportunities for preventive action

d) Suppliers

e) Audits

f) Service reports as appropriate

If the analysis of data shows that the quality management system is not suitable, adequate, or effective, Integrity Systems will use this analysis as input for improvement as required in 8.5

Records of the results of the analysis of data are be maintained.

8.5 Improvement

8.5.1 General

Integrity Systems identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system through the use of:

a) The Quality Policy
b) Quality Objectives
c) Audit Results
d) Analysis of Data
e) Corrective & Preventive Actions
f) Management Reviews

8.5.2 Corrective action

Integrity Systems takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are taken without undue delay and are appropriate to the effects of the nonconformities encountered. The Corrective Action procedure (P-852) defines requirements for

a) Reviewing nonconformities (including complaints),

b) Determining the causes of nonconformities,

c) Evaluating the need for action to ensure that nonconformities do not recur,

d) Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation (see 4.2)

e) Verifying the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.

f) Reviewing the effectiveness of corrective action taken

Recording of the results of any investigation and of action taken (see 4.2.4)

8.5.3 Preventive action

Integrity Systems determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are proportionate to the effects of the potential problems.

A documented procedure (P-853) defines requirements for:

a) Determining potential nonconformities and their causes

b) Evaluating the need for action to prevent occurrence of nonconformities

c) Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation

d) Verifying the action does not adversely affect the the ability to meet applicable regulatory requirements or the safety and performance of the medical device

e) Reviewing the effectiveness of the preventive action, as appropriate.

Records of results of any investigations and of any action taken

Related Documents

P-500 Management Responsibility

P-720 Customer Related Processes

P-821 Post Production Feedback

P-824 Internal Audits

P-825 Monitoring and Measuring of Product and Realization Processes

P-830 Control of Nonconforming Product

P-840 Statistical Techniques

P-841 Root Cause Analysis

P-852 Corrective Action

P-853 Preventive Action

P-851 Product Recall and Advisory Notices

QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST #	DATE	AUTHORIZED BY
A	ALL	ALL	ALL	00002	6/08/2011	John B Murley (0002)
B	1	1.2	a)	00072	8/11/11	John B Murley (0002)
	4	4.1		00072	8/11/11	
C	INTRO	ORG CHART	NA	00547	7/10/14	John B Murley (0002)
	4	FLOW CHART	NA	00547	7/10/14	
D	RELATED DOCUMENTS	NA	NA	00600	7/27/15	John B Murley (0002)
E	3	NA	NA	00699	12/14/16	John B Murley (0002)
F	VARIOUS	NA	NA	00768	8/22/18	John B Murley (0002)
G	VARIOUS	NA	NA	9990000067	3/17/2020	Beau Stephens (0131)
H	Various	4.2.3	NA	9990000085	7/30/2020	Beau Stephens (0131)
J	COVER	NA	NA	9990000144	4/09/2021	John B Murley (0002)
K	VARIOUS	NA	NA	9990000191	4/20/2022	John B. Murley (0002)
L	UPDATE ORG CHART	NA	NA	9990000247	12/07/2022	Beau Stephens (0131)