



QUALITY SYSTEM MANUAL

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1.0 Scope

1.1 Company Description

Integra Biotechnical, LLC is a contract medical device manufacturer with facilities located in Vista, California, U.S.A. and Tijuana, Baja California, Mexico. Integra Biotechnical LLC specializes in partnering with our customers in start-up production, improving processes, developing new process and providing “turn key” manufacturing services. We are especially suited to labor intensive assembly and packaging in a clean environment, producing products regulated by FDA, and requiring strict adherence to Good Manufacturing Practices (GMPs) and quality control.

Currently Integra Biotechnical LLC is focused to the future by pursuing process improvements, better manufacturing techniques and facilities upgrades to continually enhance the value we provide to existing and new customers. The company is determined to pursue and properly balance the disciplines of Operational Excellence, Product Leadership and Customer Intimacy as we focus on leadership principles in the markets we serve. The primary motivation behind every aspect of our efforts is a deep commitment to the process of Continual Improvement. Since the inception of the company in 1997, continual improvement has been the operating philosophy behind all that we do. Integra Biotechnical LLC is a company committed to continual improvement for our customers.

1.2 Beliefs, Visions, Mission and Goals

MISSION: Integra Biotechnical is committed to deliver a high Quality Product to our Customers (Internal and External). Quality starts with a positive personal attitude.

VISION: To be recognized as a World Class Healthcare products manufacturer by our Customers.

1.3 Quality Management System Description

Following these principles, Integra Biotechnical, LLC developed and implemented a quality management system to better identify and satisfy the needs of its customers, and it is influenced by the Medical Devices environment and changes or the risks associated with the Medical Devices environment to improve management of the company. It covers the design, production, and distribution of the company's products. The manual is divided into 8 sections corresponding to quality system requirements of the ISO standards and includes a correlation matrix between ISO 9001 - 2008, ISO 13485, Medical Devices Directives 93/42/ EEC, Canadian Medical Devices Regulations and QSR 21 CFR Part 820. Each section starts with a general policy statement expressing the commitment to implement the basic principles of the quality system element that is the subject of the section. The

general policy statement is followed by more specific procedural policies outlining how the general policy should be carried out and referencing the relevant operational procedures.

The purpose of this manual is to define and describe the quality system, to define the authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present our quality system to our customers and to inform them what specific controls are implemented to assure product quality.

2.0 Applicable Regulations and Standards

- Quality System Regulations (QSR 21 CFR Part 820).
- ISO 9001 - 2008, "Quality management systems - Requirements".
- ISO 9000 – 2005, "Quality management systems – Fundamentals and vocabulary"
- ISO 9004 – 2009, Managing for the sustained success of an organization – A quality management approach.
- ISO 13485: 2003, Medical devices -Quality management systems- Requirements for regulatory purposes.
- MEDDEV 2.12-1 Rev 6, Guidelines on a medical devices vigilance system
- Medical Devices Directives 93/42/EEC
- Canadian Medical Devices Regulations SOR/98-282.
- ISO 14971:2007, Application of Risk Management to medical devices.
- ISO 14644-1:1999, Cleanrooms and associated controlled environments- Part 1: Classification of air cleanliness.
- ANSI/AAMI/ISO 11137-1:2006, Sterilization of health care products – Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ANSI/AAMI/ISO 11135-1: 2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

3.0 Terms and Definition

External Customer: The organization Integra Biotechnical provides/delivers the best Product.

Internal Customer: Integra Biotechnical personnel/ departments that interact as a value chain to continually improve Company operations results.

4.0 Quality Management System

4.1 General Requirements

Integra Biotechnical, LLC established, documented, implements and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of the regulations/ standards documented in section 2.0

This system creates a framework for clearly defining the control of materials, processes, and verification activities, thus providing our customers with confidence that the design and manufacture of Integra Biotechnical, LLC products are performed in a well defined and controlled environment.

All personnel who manage, perform, and verify work affecting quality are responsible for implementing the quality system. The QA Manager is responsible for coordinating, monitoring, and auditing the system.

Implementation of the quality system is assessed regularly by way of internal and external audits and management reviews.

4.2 Documentation

4.2.1 General Policy

The purpose and scope of quality system documents are defined. All documents are reviewed and approved prior to issue. The quality manual and operational procedures are issued by the Quality Assurance department. Product drawings and specifications are issued by Engineering or the customer. Other documents are issued directly by the departments to which they pertain. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. The QA Manager is responsible for coordinating, enforcing, and auditing the document control-related activities.

Scope of the quality system is defined in the following documents:

- Quality manual
- Standard Operational procedures (SOPs)
- Work instructions, process procedures and internal standards
- Applicable national and international standards
- Product drawings, bills of materials, specifications, etc.
- Production and quality plans

These documents collectively define a quality system that complies with applicable regulations/ standards (referenced on section 4.1 of this manual).

Operational procedure, SOP014, Quality Records, and SOP021, Document Control, explain the purpose and the methods for controlling these documents.

4.2.2 Quality Manual

4.2.2.1 Integra Biotechnical LLC has established and maintains a quality manual. The quality manual includes the scope of the quality management system, documented procedures established for the quality management system, and describes the interaction between the processes of the quality management system.

4.2.3 Control of Documents

4.2.3.1 Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

4.2.3.1.1 Document Approval and Issue

Documents and document changes may be initiated by anyone in the organization, but they are reviewed and authorized by the same function that issued the original document. When the originator is changing a SOP (standard Operation Procedure), He/She will review the Quality System Manual (QSM 001) to ensure it is aligned to the proposed changes, obsolete documents are removed, new (or updated) documents are only issued by Quality Assurance Department. A periodic review of documents has to be done at a minimum of every two years for internal documents and procedures. For external documents an annual review is conducted to ensure document revisions are maintained current, The rules governing issuing of documents are defined in procedure SOP021, Document Control. All documents are reviewed and approved prior to issue.

4.2.3.1.2 Document Distribution

Documents are distributed electronically using a ftp site to personnel and locations where they are used. Document distribution is regulated by Procedure SOP021.

4.2.4 Control of Records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. SOP 014, Quality records procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.3 Use of quality management principles

- 4.3.2 Customer focus
- 4.3.3 Leadership
- 4.3.4 Involvement of people
- 4.3.5 Process approach
- 4.3.6 System approach to management
- 4.3.7 Continual improvement
- 4.3.8 Factual approach to decision making
- 4.3.9 Mutually beneficial supplier relationships

4.4 Regulatory Affairs

- 4.4.2 The executive management is responsible for identifying, controlling and applying for the devices licensing registrations as it may apply for selling or distribution of product in different countries. Example(s) USA, registrations of
 - Medical devices per FDA requirements QSR (510k's).
 - Canada, registration of Medical devices under section 26 of Canadian Medical Devices Regulations.
Integra Standard Operations Procedure 062 (Regulatory Affairs) Further Describes this Process.

5.0 Management Responsibility

5.1 Management Commitment

The executive management is ultimately responsible for establishing, implementing, and maintaining the quality system. Specific responsibilities comprise: formulating the quality policy, defining the organizational structure, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the quality system, and making available the resources and personnel necessary to maintain the system.

5.2 Customer Focus

The company's executive management shall ensure that the customer requirements are determined and are met with the aim of enhancing customer satisfaction.

- Conducts market research and analysis to establish the desired quality characteristics of products.
- Establishes functional specifications of products and associated services (product briefs).
- Advertises and promotes company's products emphasizing their quality aspects.
- Monitors the quality of competitors.
- Carries out contract and order reviews.
- Provides customer liaison and service. Handles customer complaints.

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5.3 Quality Policy

QUALITY POLICY

Integra Biotechnical has defined "Quality" as "Conformance to Requirements", and it is our goal to meet or exceed our customers' requirements in terms of product quality and on time delivery. The achievement of these goals demands that product quality be inherent in the design of the product and monitored throughout the manufacturing process.

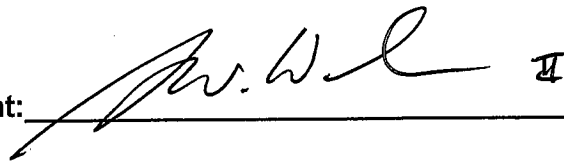
Integra Biotechnical's management is committed to providing the support and resources necessary to assure that the quality goals are consistently met and to continually improve the effectiveness of the Quality Management System.

POLITICA DE CALIDAD

Integra Biotechnical define Calidad como Conforme a los Requerimientos, y es nuestra meta cumplir o exceder los requerimientos de nuestros clientes en cuanto a la calidad del producto y su entrega a tiempo. El logro de estas metas demanda que la calidad de nuestros productos sea acorde al diseño de el producto y monitoreado a través de los procesos de manufactura.

El Equipo Gerencial de Integra Biotechnical está comprometido a proveer el soporte y los recursos necesarios para asegurar que las metas de calidad sean logradas y continuamente mejorar la efectividad del Sistema de Administración de Calidad.

President: _____



This policy has been formulated by the President of Integra Biotechnical, LLC and approved by its board of directors. The policy is explained and discussed at the general orientation training given to all existing and new employees. The policy is also posted in conspicuous locations throughout the company.

Esta política ha sido formulada por el Presidente de Integra Biotechnical, LLC y aprobada por su junta de Directores. La política es explicada y discutida en el entrenamiento y orientación general que se imparte a todos los empleados, así como también a los de nuevo ingreso. Esta política está colocada en lugares visibles en todas nuestras instalaciones.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that:

The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

President

Formulates the quality policy.

Initiates and supervises the quality system.

Provides resources necessary to maintain the system.

Conducts management reviews of the quality system.

Marketing & Sales

Conducts market research and analysis to establish the desired quality characteristics of products.

Establishes functional specifications of products and associated services (product briefs).

Advertises and promotes company's products emphasizing their quality aspects.

Monitors the quality of competitors.

Carries out contract and order reviews.

Provides customer liaison and service.

Handles customer complaints.

Engineering

Prepares product specifications from product briefs or customer-specified requirements.

Designs products:

Initiates design reviews.

Verifies and tests the designs.
Documents design outputs.

Material Management

Manages Receiving and Shipping
Manages Inventory Control
Prepares production forecasts and scheduling.
Manages Purchasing department
Selects qualified supplies and subcontractors.
Prepares and approves purchasing documents.
Verifies quality and quantity (catalog items only) of received goods.
Monitors and assesses supplier performance.

Manufacturing

Determines production personnel and equipment requirements.
Controls and monitors processes.
Defines workmanship standards.
Maintains production equipment.
Administrates storage areas.
Performs production engineering.
Prepares production plans.
Prepares quality plans.

Customer Service

Processes servicing orders.
Performs servicing.
Collects field performance and reliability data.
Administrates servicing.
Collects field performance and reliability data.

Human Resources

Defines personnel qualification requirements.
Implements measures to motivate personnel.
Conducts training.

Quality Assurance

Establishes and maintains the quality management system.
Audits implementation of the quality system.
Initiates requests for, and follows up on, corrective actions.
Maintains and calibrates measuring and test equipment.
Carries out supplier quality surveys and audits.
Performs inspections and testing in accordance with the quality plans.
Handles nonconforming products.
Coordinates document control activities.
Maintains inspection records.

Finance and Accounting

Manages Accounts Payable (AP) and Accounts Receivable (AR).

Prepares monthly and annual financial reports.

Financial Planning

Interrelation of personnel who manage, perform, and verify work affecting quality is defined in the organizational chart enclosed at the end of this section.

Note: Job descriptions are formulated by the Department managers and reviewed with personnel for clearly definition of their duty, responsibility and authority to detect, correct and prevent any objectionable conditions.

5.5.2 Internal Communication

Internal communication is maintained through regular management meetings, quarterly and annual review with all company employees.

5.6 Management Review

5.6.1 General

The company's executive management reviews the quality system at planned intervals. The purpose of the reviews is to ensure the continuing suitability, adequacy and effectiveness of the quality management system. This review is taken as a chance to assess opportunities for continual improvement and the need for changes to the quality management system. The President is responsible for scheduling and conducting the reviews. The schedule of reviews is intended to facilitate the timely provision of data in the context of strategic planning for the company. Inputs to the review process result in outputs that extend beyond the effectiveness and efficiencies of the quality management system. Outputs from reviews provide data for use in planning for performance improvement of the company.

Records from management reviews are maintained. Details for scheduling, conducting, and recording the reviews are provided in Procedure SOP002, Management Review.

Integra Biotechnical, LLC appoints as the Management Representative the Quality Assurance and Regulatory Affairs (QA/RA) Manager. She or he has the authority and responsibility to ensure that the quality management system is maintained and its efficiency is continually improved, and that the system always complies with the requirements of regulations and standards referenced on section 4.1. She or he has the

authority and responsibility to report to top management on the performance of the quality management system and the need for improvement, this can be done during the Management Review. She or he is required to promote the awareness of regulatory and customer requirements throughout the organization.

5.6.2 Review Input

The top management of Integra Biotechnical LLC selects input to evaluate efficiency as well as effectiveness of the quality management system. This input considers the customer (both internal and external) and includes, but are not limited to:

- Results of audits
- Customer feedback, on time delivery
- Customer Complaints vigilance and Medical Devices Reports.
- Customer Surveys responses.
- Process performance and product conformity
- Suppliers performance (FPY)
- Environmental monitoring
- Status of preventative and corrective actions
- Follow-up actions from previous management review
- Other factors that may impact the organization and could affect the quality management system, such as financial, social or environmental conditions, and relevant statutory and regulatory changes
- Recommendations for improvement

Details of the review input are provided in Procedure SOP002, Management Review.

5.6.3 Review Output

By extending management review beyond verification of the quality management system, the outputs of management review are used by the top management of Integra Biotechnical LLC as inputs to improvement processes. Top management identifies opportunities for performance improvement of the company by using the review process.

The output from the management review includes any decisions and actions related to improvement of the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, and resource needs.

Details of the review output are provided in Procedure SOP002, Management Review.

6.0 Resource management

6.1 Provision of Resources

6.1.1 Introduction

The top management of Integra Biotechnical LLC is resolved to ensure that the resources essential to the implementation of strategy and the achievement of the company's objectives are identified and made available. Integra Biotechnical, LLC has determined and provides the resources needed to implement and maintain the quality management system and continually improve its effectiveness, and to enhance customer satisfaction by meeting regulatory and customer requirements. These resources include people, infrastructure, work environment, information, suppliers and partners, natural resources, and financial resources. Provision of resources is reviewed at regular management review meetings.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

The Integra Biotechnical LLC quality management organization is comprised of the following seven departments:

- Marketing & Sales department headed by the President of the company.
- Manufacturing & Engineering departments headed by the Manufacturing Manager.
- Vice President of Operations is responsible for: Manufacturing, Materials, Purchasing, Production Control, Warehousing, and Facilities departments.
- Customer Service department headed by the Customer Service Manager
- Human Resources department headed by the Human Resources Manager
- Quality Assurance (QA) department headed by the QA/RA Manager

- Finance and Accounting department headed by the Accounting Manager.

Each department head reports directly to the President. The President and the department heads constitute the top management. An Organization Chart shall be authorized by the President and maintained on file in the Quality Assurance department and made available as may be deemed appropriate by the President and/or Quality Assurance Manager.

6.2.2 Competence, Awareness and Training

Integra Biotechnical LLC determines the necessary competence for personnel performing work affecting product quality, provide training or take other actions to satisfy these needs. The company shall evaluate the effectiveness of the actions taken, and ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Personnel assigned to perform specific tasks are qualified on the basis of appropriate education, training, or experience. Records of personnel qualifications, education, skills and training are maintained. SOP 006 further describes this process.

Procedural Policies

Training Needs

All employees are assessed by their supervisors and managers to determine if their qualifications are adequate and if they need to be supplemented by additional training. Occurrences of product non-conformities and problems with operations and processes also provide data for determining employee-training needs.

Training Program

Integra Biotechnical, LLC provides employee orientation training to all new employees. The training includes explanations of how the quality system works and how the employee should use and maintain the system. Training in skills and knowledge required to perform specific tasks is provided to employees directly by their departments. Procedure SOP006, Personnel Training, describes in detail the training programs provided by Integra Biotechnical, LLC

Training Records

The Personnel department maintains records of all internal and external training provided to employees.

6.3 Infrastructure

Integra Biotechnical LLC determines the infrastructure (including Information systems) necessary for the realization of products while considering the needs and expectation of customers and regulatory requirements. Procedures SOP 007 and 044 address the infrastructure needs, Procedure SOP 047 addresses the requirement for software validations, Procedure SOP 070 address the Information Technology Requirements. Production and process equipment is checked and maintained to ensure continuing process capability; the relevant activities are regulated by SOP 023. Since natural phenomena that cannot be controlled can impact the infrastructure Integra Biotechnical LLC has adopted a strategy to mitigate the risk and impact of such an occurrence, the details of this are provided in SOP 065, Emergency Management, Disaster/Recovery Plan procedure..

6.4 Work Environment

Top management ensures the work environment has a positive influence on motivation, satisfaction and performance of people in order to enhance the performance of the company. The following are considered in the creation of a suitable work environment:

- Workplace location and layout
- Temperature, light, airflow
- Hygiene, cleanliness
- Safety rules and guidance

In order to achieve this production equipment and machines are regularly maintained following the schedules and recommendations provided by their manufacturers, as described in SOP 012. Performance and accuracy of the equipment is continually monitored, per SOP 023 and 051. Suitable production environment is ensured by proper maintenance of buildings and HVAC equipment, as stipulated in SOP 008 and 044, and by regular cleaning and clearing of the production areas, described in SOP 009 and 010

7.0 Product Realization

7.1. Planning of Product Realization

Integra Biotechnical, LLC maintains a documented quality management system designed and implemented to fulfill the regulations and standards referenced in section 2.0. This system creates a framework for clearly defining the control of materials, processes, and verification activities, thus providing our customers with confidence that the design, and manufacture, of Integra Biotechnical, LLC products are performed in a well defined and controlled environment. Inspection

and testing are conducted when purchased materials and components are received, at significant stages of production, and prior to dispatch of finished products. The objective of inspections and testing is to verify product conformance with specified requirements. Materials, components, subassemblies, and finished products are prevented from use, assembly, and dispatch until the required inspections are completed. Records of inspections are established and maintained to evidence that products comply with stated requirements.

Integra Biotechnical complies all regulatory requirements according to customer required distribution of the product:

- USA Distribution
- Canada
- EU

SOP 036 (Shipping Procedure) and SOP 050 (Final product Release) describes this process.

7.2. Customer-Related Processes

7.2.1 Determination of requirements related to the product.

The Customer Service Department is responsible for receiving and processing all customer orders. Orders for standard catalog products are reviewed and further processed by Customer Service. Orders for custom products are reviewed by the Sales Manager. Engineering, Production, Materials Management and Quality Assurance may be called to assist with the review of orders for custom products. As a minimum, every design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations. Design verification activities are described in Procedure SOP022.

7.2.2 Review of requirements related to the product.

For both categories of products, the order (contract) reviews comprise verification that the customer's requirements are adequately defined and documented, and have been well understood, and that the company has the capacity to meet the contract requirements. Contract reviews are governed by Procedure SOP019, Receiving Orders and Contract Review for Standard and Custom Products.

Change orders are received and reviewed by the same functions that are responsible for the review of initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements. Operational procedure SOP019 provides detailed instructions about how to process change orders.

7.2.3 Customer communication

The Customer Service Department is responsible for receiving and processing all customer orders. Maintain customer contact through:

- review of customer contact,
- customer questionnaire response,
- customer complaints
- advisory notices

Refer to Customer Focus (SOP 059) procedure and Customer Complaint (SOP 037) procedure, Medical Devices Vigilance System (SOP 052) procedure.

7.3 Design and Development

7.3.1 Design and development planning

The design input may be provided to Engineering in two ways. Design input for company's standard catalog products comes from Marketing in the form of a product brief. Custom products are specified by Sales using a design order. Establishment of product briefs and design orders is governed by Procedure SOP022.

The Engineering Manager or designee is responsible for the planning of design projects, including assignment of design activities and control of organizational and technical interfaces.

7.3.2 Design and development inputs

As a minimum, design and development input shall include the following:

- functional and performance requirements,
- risk and safety analysis (Process FMEA),
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs,
- Other requirements essential for design and development.

Design and development inputs activities are described in Design Control SOP022.

7.3.3 Design and development outputs

Design output is documented on two levels: Primary output consists of documents defining the designed product, while the secondary output supports the design with calculations, analysis, etc. Design output documents are checked and approved before they are released for production. Establishment, verification, and release of design output are governed by Procedure SOP022.

7.3.4 Design and development review

Design changes are initiated using Engineering Change Request (ECR) forms. ECRs may be requested by department managers or Engineering itself. The ECR provides design input for designing the change. Planning, design, and design verification activities follow the same rules as apply to original designs, as documented in Procedure SOP022.

7.3.5 Design and development verification

As a minimum, every design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations. Design verification activities are described in Procedure SOP022.

7.3.6 Design and development validation

As a minimum, every design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations. Design verification activities are described in Procedure SOP022.

7.3.7 Control of design and development changes

Design changes are initiated using Engineering Change Request (ECR) forms. ECRs may be requested by department managers or Engineering itself. The ECR provides design input for designing the change. Planning, design, and design verification activities follow the same rules as apply to original designs, as documented in Procedure SOP022.

7.4 Purchasing

7.4.1 Purchasing process

Assessment and quality performance monitoring of suppliers are carried out by the Purchasing department. Subcontractors are assessed and monitored jointly by Purchasing and QA. The system for assessing and

monitoring vendors is defined in procedure SOP024, Purchasing, Supplier Assessment and Supplier Control Procedure.

7.4.2 Purchasing information

Quality capabilities and references of suppliers and subcontractors are assessed before orders for supply of materials, components, and services are placed. Quality performance of all suppliers and subcontractors is continually monitored. Vendors showing inadequate performance are asked to implement corrective actions, and are discontinued if there is no improvement.

7.4.3 Verification of purchased product

Purchasing maintains an approved supplier and subcontractor list. Orders may only be placed with vendors that are on the list. In-process inspections are specified on Work Instructions, DHR's accompanying products during their manufacturing processes and operations. The inspections can be carried out by the production personnel or Quality Control. All activities related to the in-process inspections are regulated by Procedure QOP001, In-process Inspections.

7.5 Production And Service Provision

7.5.1 Control of production and service provision

Production and individual operations are planned and documented. Personnel performing complex or critical operations are provided with work instructions and, when applicable, workmanship criteria. Special processes are controlled and are carried out in accordance with written procedures. Production and process equipment is checked and maintained to ensure continuing process capability. Production areas are regularly cleaned to provide a suitable production and working environment.

7.5.2 Validation of processes for production and service provision

Production processes are controlled by written process procedures, process operator training and/or certification, process equipment qualification, or continual process monitoring and statistical analysis.

Any Production processes where the resulting output cannot be verified by subsequent monitoring or measurement is validated, the purpose of the validation is to demonstrate with objective evidence the ability of these processes to achieved planned results, Procedure SOP 022

defines the criteria for review/approval of validation plans (IQ/OQ/PQ Protocols and Completion Reports) and the requirements for revalidation.

No process change is allowed unless authorized by customer.

7.5.2.1 Installation and servicing

Integra Biotechnical excludes this section from its Quality system because the company only provides a manufacturing service and the products built are intended for use by technical personnel

7.5.3 Identification and traceability

Materials, components, subassemblies, and products are identified by a part number correlated to corresponding drawings, specifications, and other technical documents. Finished products are uniquely identified by lot numbers. SOP 017 procedure, describes the process for product identification and traceability.

Inspection status of a product is identified to assure that only product that has passed inspection is used, installed, or dispatched. Authority responsible for the release of conforming product is defined.

Returned Goods are segregated and identified to distinguish them from conforming product, SOP 038 describes the process for handling returned goods.

7.5.4 Customer property

Integra Biotechnical LLC shall exercise care with customer property while it is under the control or being used by the company. Examples of such property are:

- ingredients or components supplied for inclusion in a product,
- product supplied for repair, maintenance or upgrading,
- packaging materials supplied directly by the customer,
- customer materials handled by service operations such as storage,
- services supplied on behalf of the customer, such as transport of customer property to a third party, and
- Customer intellectual property, including specification, drawings, proprietary information and personal data.

All activities related to the customer property are regulated by procedures SOP012, Maintenance, Manufacturing Equipment, SOP017, Product Identification and Traceability and Lot Number Control, SOP021, Document Control; Internal, Redline and External, SOP026, Receiving,

SOP027, Customer Supplied Product, SOP034, Non-Conforming Material Report, SOP033, Component and In-process Material Control, SOP035, Product Handling and Preservation and Storage Areas. Intellectual property shall be preserved in accordance with Confidentiality Agreements.

7.5.5 Preservation of product

Customer supplied products are handled in the same manner as other products purchased for incorporation into the supplies. When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures. Loss, damage, or unsuitability of a customer's products is recorded and reported to the customer.

The stockrooms and storage areas, and their operation, are the responsibilities of the Materials Manager. Only products that are properly identified and that have passed the mandatory inspections are authorized to enter and leave the stockrooms. Every three months the stockrooms are cleaned up and are inspected to assess the condition of stock. Procedure SOP035, Product Handling and Preservation and Storage, governs the operation of stockrooms and storage areas, and the assessments of stock.

Packaging is specified by the Engineering department. The specifications are communicated to the shipping personnel in the form of drawings and work instructions. Packaging is designed for the intended means of delivery.

After the final inspection, products are protected and stored in adequate conditions to prevent damage and deterioration. If delivery is specified, it is subcontracted only to pre-qualified shippers.

The activities of packaging and delivery are governed by Procedure SOP036, Packaging and Delivery-(Shipping).

7.6 Control of monitoring and measuring devices

All measuring and test equipment, comparative references (such as gauges and templates) are regularly calibrated and/or checked. Equipment used for purposes other than verification of products or control of production processes is exempted from the requirement for calibration. Such equipment is labeled with stickers warning that it is not calibrated. Uncontrolled measuring equipment may not be stored in inspection areas. These activities are governed by SOP 012, Maintenance manufacturing equipment procedure and SOP 013, Inspection, measuring and test equipment procedure. Where computer software is used for verification of products and for controlling of production processes a validation

will be conducted per SOP 047 to document the software configuration management to maintain its suitability for use and to verify the intended application is achieved.

8.0 Measurement, Analysis and Improvement

8.1 General

Integra Biotechnical LLC shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. This process is described in SOP002, Management Review, QOP 005, Statistical Technics and SOP 064, Cost Improvement procedure.

All purchased products are subjected to either a one- or a two-stage receiving inspection. First all products are inspected visually by the warehouse clerk, and then critical products and products that have been custom manufactured to Integra Biotechnical, LLC requirements are subjected to a more detailed and technical QC inspection. Nonconforming products are segregated and are prevented from use in production. Procedure RIP001, General Receiving Inspection, sets forward detailed rules for performing and recording receiving inspections.

The Quality Assurance department identifies the need for the use of statistical techniques. Statistical techniques may be needed in controlling production processes and establishing inspection-sampling procedures. When required and directed by the QA department, statistical techniques are employed in process control and analysis. Personnel performing process control are provided with charts, tables, and other instructions in the use of the relevant statistical techniques. Procedure QOP005, Statistical Techniques, governs the application of statistical techniques to process control.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system Integra Biotechnical LLC monitors information, Customer Questionnaire, customer complaints and customer feedback, was relating to customer perception as to whether the organization has met customer requirements. The method for obtaining and using this information is described in the procedures SOP002, Management

Review, SOP037, Product Complaints, SOP052, Medical Device Vigilance System and SOP059, Customer Focus.

8.2.2 Internal audit

8.2.2.1 General Policy

Integra Biotechnical, LLC conducts internal audits at planned intervals to determine if the quality management system conforms to the planned arrangements, to the requirements of ISO 9001 and ISO 13485 and to the quality management system requirements established by the company, and is effectively implemented and maintained. Comprehensive, planned, and documented quality audits are carried out at least once a year. Audits are scheduled on the basis of the status and importance of the activity. The audits are conducted by personnel independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and, if appropriate, a corrective action is requested. The management responsible for the areas being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the actions taken and the reporting of verification results. The required activities are described in SOP005, Internal Audit.

8.2.2.2 Procedural Policies

8.2.2.2.1 Planning and Scheduling

8.2.2.2.1.1 The QA Manager establishes the internal audit plan and schedule in accordance with Procedure SOP005, Internal Audits. Every activity and area is audited at least once a year. Selected activities may be audited more frequently, depending on their importance and quality performance history.

8.2.2.2.2 Audit Team and Preparation for Audit

8.2.2.2.2.1 Only personnel independent of the audited activities are assigned to conduct the internal audits. Normally, the QA Manager leads the audit team except when QA activities are being audited. Audits of QA activities are

conducted by the President or the Engineering Manager.

8.2.2.2.2 Auditors prepare for audits by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires and checklists. Selection of auditors and preparation for the audit are explained in Procedure SOP005, Internal Audits.

8.2.2.3 Conducting the Audit

8.2.2.3.1 Auditors seek objective evidence whether the audited activities comply with the requirements of the documented quality management system. The evidence is collected by observing the activities, interviewing personnel, and examining quality records.

8.2.2.3.2 Nonconforming conditions are documented and recorded using the Integra Biotechnical Internal Audit Form (Form001).

8.2.2.3.3 Audits are conducted in a way that minimizes disruption of the audited activities.

8.2.2.4 Corrective Action and Follow-up

8.2.2.4.1 When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement a corrective action, and ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate nonconformities and their causes. Implementation and effectiveness of the action is verified by a follow-up audit. The Integra Biotechnical Internal Audit Form (Form001) is used for monitoring and recording implementation of the corrective actions.

8.2.3 Monitoring and measurement of processes

8.2.3.1 Integra Biotechnical, LLC applies suitable methods for monitoring and, where applicable, measurement of 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 shall be taken, as appropriate, to ensure conformity of the product. Procedures SOP002, Management Review, SOP023, Process Control and SOP042, Corrective and Preventive Action, QOP001, In-process Inspection and QOP002, Final Inspection, describe the required activities.

8.2.3.1.1 The Quality Assurance department identifies the need for the use of statistical techniques. Statistical techniques may be needed in controlling production processes and establishing inspection-sampling procedures. When required and directed by the QA department, statistical techniques are employed in process control and analysis. Personnel performing process control are provided with charts, tables, and other instructions in the use of the relevant statistical techniques. Procedure QOP005, Statistical Techniques, governs the application of statistical techniques to process control.

8.2.4 Monitoring and measurement of product

8.2.4.1 Integra Biotechnical, LLC 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.

8.2.4.1.1 In-process inspections are specified on Work Instructions, DHR's accompanying products during their manufacturing processes and operations. The inspections are carried out by the production personnel or Quality Control personnel. All activities related to the in-process inspections are regulated by Procedure QOP001, In-process Inspections.

8.2.4.1.2 All finished products are subjected to the final QC inspection. First the inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily, and then they perform the remaining inspections and tests necessary to complete the evidence that products conform to specified requirements. Product release and services delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. Performing and recording the final inspection is regulated by Procedure QOP002, Final Inspection. Final Product Release is regulated by procedure SOP 050, Final Release.

8.2.4.2 Carrying out the inspections, the QC inspectors and production personnel use appropriate and calibrated measuring and testing equipment. For complex inspection operations, inspectors are provided with inspection procedures and/or checklists (issued as work instructions).

8.2.4.3 Evidence of conformity with the acceptance criteria is maintained. All three types of inspections are concluded with establishment of an inspection record. Rules for establishing these records are described in procedures RIP001, QOP001, and QOP002 (or Applicable Customer specific QOP). Filing and maintenance of inspection records are regulated by Procedure SOP014, Quality Records.

8.3 Control of nonconforming product

8.3.1 General Policy

8.3.1.1 Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Responsibility for disposition of nonconforming product is defined and, when required, the customer is contacted for concession. Repaired or reworked product is re-inspected. Procedure SOP 034, Non Conforming material Report procedure governs all aspects of non conforming material handling/control/final disposition.

8.3.2 Procedural Policies

8.3.2.1 Identification and Documentation

8.3.2.1.1 Integra Biotechnical, LLC identifies and documents all non-conformities, regardless of how insignificant they seem to be or how easily they can be repaired. The nonconformity reports are an invaluable tool in tracking performance and trends that give indication where and when a corrective action is required.

8.3.2.1.1.1 Nonconforming products are documented using a non-conformity report form. The use of the form and its processing are explained in Procedure SOP034, Non Conforming Material Report Procedure.

8.3.2.1.1.2 To prevent nonconforming products from being used or shipped, they are marked with an ON HOLD label and are segregated.

8.3.2.2 Nonconformity Review and Disposition

8.3.2.2.1 Material Review Board is responsible for providing the product/material disposition and for review/ approval of rework instructions according to Integra procedure SOP034, this procedure provides further detailed rules for nonconformity review, disposition decision, and for recording these activities.

8.3.2.2.2 The customer is contacted for acceptance by concession of a nonconforming product.

8.3.2.3 Reprocessing will be done following written and approved rework instructions..

8.3.2.4 Re-inspection

8.3.2.4.1 When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements. Repaired or

reworked products are re-inspected in accordance with procedure SOP034, Non Conforming Material Report procedure, as applicable.

8.4 Analysis of Data

8.4.1 General Policy

Integra Biotechnical, LLC determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

8.4.2 Procedural Policies

This includes data generated as a result of monitoring and measurements described in Procedure SOP002, Management Review. The analysis of data provides information relating to customer satisfaction, conformity to product requirement, characteristics and trends of processes and products including opportunities for preventive action, and suppliers.

8.5 Improvement

8.5.1 Continual Improvement

8.5.1.1 General Policy

Integra Biotechnical LLC continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventative actions. Procedure SOP002, Management Review, describes the process for collecting, analyzing and acting on the data.

8.5.1.2 Procedural Policies

Continual Improvement Philosophy – Continual Improvement is the company philosophy that challenges us to continually improve all aspects of our business. This belief pervades the entire organization and is the motivation behind our actions. We believe Continual Improvement is a never-ending process and a permanent part of our culture.

Continual Improvement Objectives - Our Continual Improvement objectives are:

- Quality of Products and Services
- On Time Delivery
- Waste Reduction
- Quality of Work Life
- Growth of People, Processes, and Product Markets

Continual Improvement Strategies - Our Continual Improvement strategies are:

- Quality System Focus – to meet our Quality Policy and Quality Objective.
- Just-In-Time Principles – to meet Delivery and Waste Continual Improvement Objectives.
- Preventative Maintenance – to meet Delivery, Waste, and Quality Continual Improvement Objectives.
- Employee Involvement – to meet Work Life and Growth Continual Improvement Objectives.

Quality System Focus – Our Quality System Focus is to:

- Provide consistently conforming products and services.
- Continue to be ISO 9001 compliant.
- Enhance supplier – customer relationships (internal and external).
- Apply Quality at the Source concepts so every individual can make these statements:
 - ◆ “I have a complete and accurate understanding of customer requirements.”
 - ◆ “I have the ability to verify that I am meeting those requirements.”
 - ◆ “I know that I am responsible for quality.”

Continual Improvement Linkage – We believe that maintaining ISO registration supports the philosophy of Continual Improvement. Linking ISO focus with Continual Improvement allows us to:

- Create awareness of current practices which allows for improvement;
- Reduce waste through standardization;
- Document the Quality Management System and the training support; require corrective and preventive action.

8.5.2 Corrective/Preventive action

8.5.2.1 General Policy

Causes or potential causes of product and quality system non-conformities are investigated and Corrective/Preventive actions are implemented to prevent their recurrence. Processes, work operations, quality records, service reports, and customer complaints are analyzed to detect any sources of potential quality problems. Controls are applied to ensure that corrective and preventive actions are implemented and that they are effective.

8.5.2.2 Procedural Policies

8.5.2.2.1 Initiation of Corrective/Preventive Actions

8.5.2.2.1.1 Anyone in the company may propose initiation of corrective/preventive actions, but only the President and the QA/RA Manager can authorize and request their implementation.

8.5.2.2.1.2 Corrective/Preventive actions may be initiated as the result of identification of product nonconformity, problems with a process or operation, non-compliances observed during audits, customer complaints, nonconforming deliveries from suppliers or subcontractors, and other occurrences of non-complying conditions. SOP042, Corrective and Preventive Action procedure, provides a complete list of the relevant non-complying conditions, and describes in detail the rules that apply to initiating a corrective/preventive action.

8.5.2.2.2 Records

8.5.2.2.2.1 The required records of the results of actions taken are described in Procedure SOP042.

8.5.2.2.3 Follow Up

8.5.2.2.3.1 Every corrective action is followed up by t
the QA/RA Manager or designee to
determine if the action has been
implemented and if it is effective.

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History Change:

Rev	Change	DCO #	Date
A	Initial Release	107	3/5/99
B	Update Procedure	116	4/20/99
C	To reference EN46001 in Appropriate Documents	120	5/19/99
D	To Remove Inconsistencies and Update Org. Chart	220	7/18/00
E	Remove Section Rows, Remove Org. Chart	281	5/31/01
F	Update Procedure	312	12/27/01
G	To add RedLine	349	5/23/02
H	Implementation of ISO 9001 and ISO 9001:2000 and ISO 13485:2003	480	11/28/03
I	Section 1.3 Remove " Installation" Update "Continuous or Continuously" by "Continual or Continually"	484	12/03/03
J	Implement the process for obtaining Canadian License for selling Medical Devices in Canada.	573	11/1/04
K	Add References to MDD's and Canadian MDR's	578	11/4/04
L	Change vista facility Address and change Mexico Facility Name. Section 7.5.1. Delete reference to service provisions. Section 7.5.2 adds "No process change allowed unless authorized by customer". Correct ISO 9000:2004, shall be ISO 9004:2000	920	6/7/06
M	Add new (additional) facility address, Remove section 1.4 , Add MEDDEV current revision (Rev 5) –section 2.0-, update ISO 13485 revision for CMDCAS, relocate section 5.5.2 inside section 5.6.1, update section 8.5.3.3	1420	11/27/07
N	Implement Canadian regulations reference and add Part 820 description in the QSR title in Appendix I. Update Organization Chart in Appendix III, Add section 7.5.2.1 (Installation and Servicing)	1704	9/09/08
O	Update section 8.3.2.1/8.3.2.2.4 for harmonization with SOP034	1771	11/06/08
P	Font type corrections in all sections titles to bold, Section 2.0 and 4.1: update revision ISO:9001:2008 and MEDDEV 2.12-1 Rev 6, Add ISO: 14971: 2007 Section 4.2.3.1.2: Add "electronic distribution" section 7.1: add CMDCAS and 93/42/EC Section 7.3.1 add "Or designee" Section 7.4.1: Remove reference to SOP 025 (Obsolete), Sections 7.5.4, 8.3.2.1.1.1 and 8.3.2.4: update SOP 034 Title "Non Conforming material report" procedure, section 8.1: Add QOP 005 and SOP 064, section 8.2.4.1.2: Add SOP 050 Section 8.3.2.3: Remove reference to SOP 030 (Obsolete). Sections 1.3, 6.3, 7.5.4, 7.6, And 8.2.2.2.4.1: add ISO 9001: 2008 New requirements. Appendix III, update organizational chart, customer service manager added and removed Engineering manager (function to be executed by the process Engineer).	2912	10/06/10
Q	Consolidate into one section (2.0) the reference to the applicable standards and regulations (Add ISO , rename the section as : Applicable Regulations and Standards , delete reference to the standards and regulations in section 4.1 Correct typographical error (incorrect Rev level "O" in the appendixes sections).	2936	10/15/10

R	<p>Change company name in Mexico: Delmar Medical to Integra Biotechnical</p> <p>Correct typing errors in the following sections: 2.0, 4.2.1, Section 4.2.3.1.1; implement a review of the Quality Manual affected section when a SOP change is being proposed, implement a periodic review of documents (minimum every 2 years) and an annual review of external documents (such standards).</p> <p>Section 4.2.3.1.2; remove the use of distribution lists</p> <p>Section 4.2.4; Add the reference to SOP 014 quality records procedure</p> <p>Section 5.0; update the job description requirements to ensure a clearly definition of personnel duty, responsibility and authority to detect, correct and prevent any objectionable conditions.</p> <p>Section 5.6.2; Update the review input elements to match with management review agenda requirements</p> <p>Section 6.2.1; Update Management organization description to match with organization chart in appendix III of this procedure.</p> <p>Section 6.3; Add reference to SOP 070 Information Technology procedure</p> <p>Section 7.1.1; Replace the word "Fulfill" with "Integra Biotechnical complies" and add reference to SOP 050, final product release</p> <p>Section 7.5.2; Add the explanation for process validation and the reference to SOP 022 for revalidations requirements.</p> <p>Section 8.2.4.3; Add the reference to applicable Customer specific QOP</p> <p>Section 8.3.1.1; Add the reference to SOP 034, NCMR procedure</p> <p>8.3.2.2.1 Add information from section 8.3.2.2.4 and document the review/approval of rework instructions.</p> <p>Section 8.3.2.2.2; Remove the types of disposition and reassign the sequential section numbers.</p> <p>Section 8.3.2.2.4; Remove since it was included in updated section 8.3.2.2.1</p> <p>Sections 8.5.2, 8.5.2.2.1.1, 8.5.2.1.2, 8.5.2.2.3.1; Add "Preventive" and remove section 8.5.3 since its content was implemented into section 8.5.2</p>	3918	11/03/11
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APPENDIX I – STANDARDS CORRELATION MATRIX

ISO 9001:2008	CAN / CSA- ISO 13485-2003, Quality System – Medical CMDCAS Devices ISO 13485: 2003	QSR, 21 CFR Part 820	MDD Council Dir.93/42/EEC)
4.1 General requirements	4.1 General requirements	820.5 Quality System	
4.2 Documentation requirements (title only)	4.2 Documentation requirements (title only)		
4.2.1 General	4.2.1 General	820.20 (e) Quality System Procedures	
4.2.2 Quality Manual	4.2.2 Quality Manual	820.20 Management Responsibility	
4.2.3 Control of documents	4.2.3 Control of documents	820.40 (a,b) Document control	Annex II, Section 6.1
4.2.4 Control of records	4.2.4 Control of records	820.180 (a,b) Records General requirements	Annex II, Section 6.1
5 Management Responsibility (title only)	5 Management Responsibility (title only)		
5.1 Management commitment	5.1 Management commitment	820.20 Management Responsibility	
5.2 Customer focus	5.2 Customer focus	820.20 (b –1,2,3) Management responsibility	
5.3 Quality Policy	5.3 Quality Policy	820.20 (a) Quality Policy	
5.4 Planning (title only) 5.4.1 Quality objectives 5.4.2 Quality management system planning	Same requirements given in ISO 9001: 2000 apply.	820.20 (a, d) Quality Planning	
5.5 Responsibility, authority and communication (title only) 5.5.1 Responsibility and authority 5.5.2 Management representative 5.5.3 Internal communication	5.5 Responsibility, authority and communication (title only) 5.5.1 Responsibility and authority 5.5.2 Management representative 5.5.3 Internal communication	820.20 (b 1,3) Responsibility and authority, Management representative	
5.6 Management review (title only) 5.6.1 General 5.6.2 Review input 5.6.3 Review output	5.6 Management review (title only) 5.6.1 General 5.6.2 Review input 5.6.3 Review output	820.20 (c) Management review	
6 Resource management (title only)	6 Resource management (title only)		

APPENDIX I – STANDARDS CORRELATION MATRIX

ISO 9001:2008	CAN / CSA- ISO 13485-2003, Quality System – Medical CMDCAS Devices ISO 13485: 2003	QSR, 21 CFR Part 820	MDD Council Dir.93/42/EEC)
6.1 Provision of resources	6.1 Provision of resources	820.20 (b (2)) Organization, Resources	
6.2 Human resources (title only) 6.2.1 General 6.2.2 Competence, awareness and training	6.2 Human resources (title only) 6.2.1 General 6.2.2 Competence, awareness and training	820.25 Personnel	
6.3 Infrastructure	6.3 Infrastructure	820.70 (c, e, f, g) Production and Process controls	Annex I (Sections 8.4, 8.5)
6.4 Work environment	6.4 Work environment	820.070 (a, c, d, e, f, g) Production and process controls	Annex I (Sections 8.4, 8.5)
7 Product realization (Title only)	7 Product realization (Title only)		
7.1 Planning of product realization	7.1 Planning of product realization	820.20 (a, d) Quality Planning 820.80 (a) Receiving, in-process, and finished device acceptance	
7.2 Customer related processes (title only) 7.2.1 Determination of requirement related to the product 7.2.2 Review of requirements related to the product 7.2.3 Customer communication	7.2 Customer related processes (title only) 7.2.1 Determination of requirement related to the product 7.2.2 Review of requirements related to the product 7.2.3 Customer communication	820.160 Distribution	Annex I (Sections: 1-14)
7.3 Design and development (title only) 7.3.1 Design and development planning 7.3.2 Design and development inputs 7.3.3 Design and development outputs 7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation 7.3.7 Control of design and development changes	7.3 Design and development (title only) 7.3.1 Design and development planning 7.3.2 Design and development inputs 7.3.3 Design and development outputs 7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation 7.3.7 Control of design and development changes.	820.30 (d) Design output 820.30 (e) Design review 820.30 (f) Design verification 820.30 (g) Design validation 820.30 (h) Design transfer 820.30 (i) Design changes 820.30 (j) Design history file	

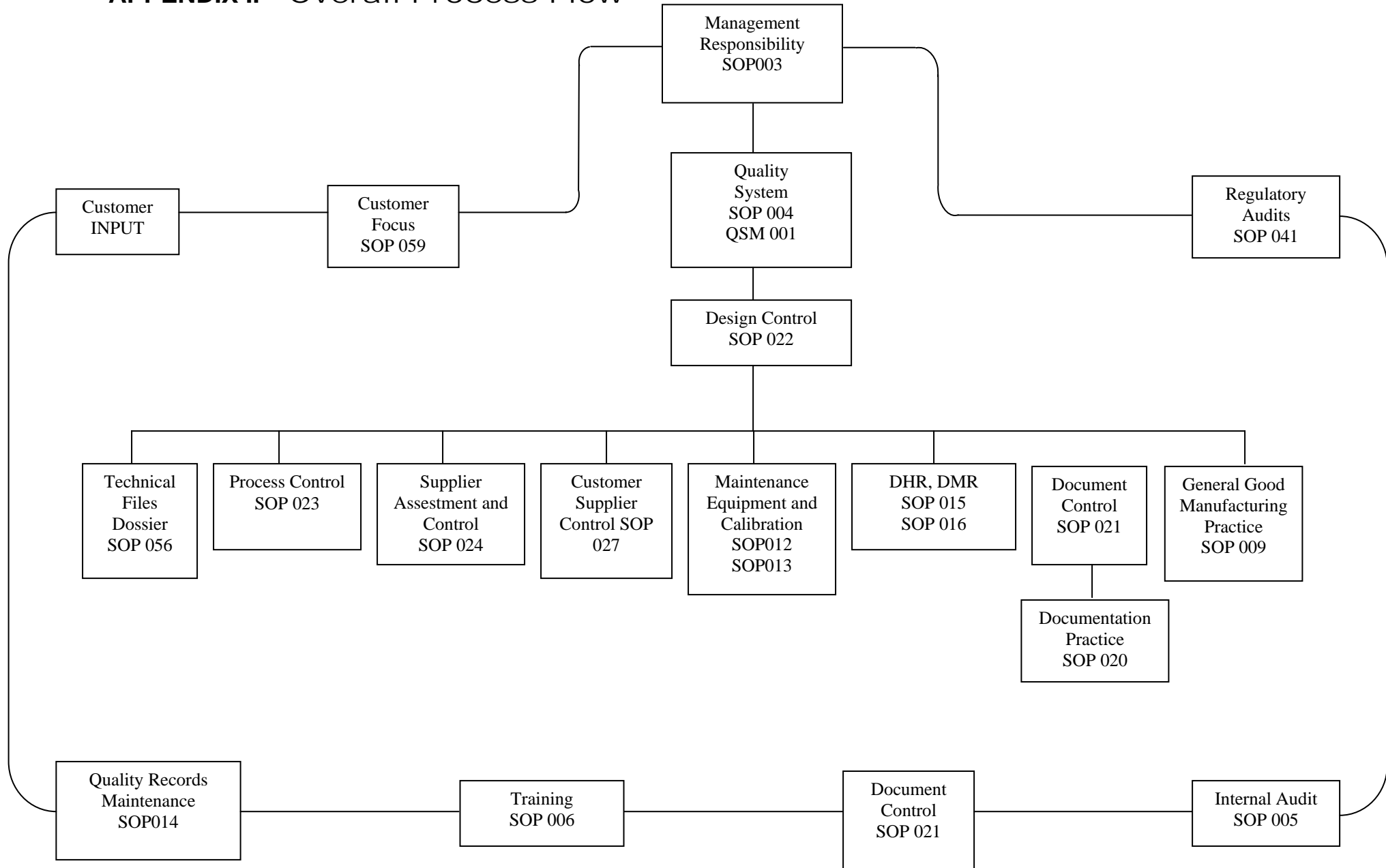
APPENDIX I – STANDARDS CORRELATION MATRIX

ISO 9001:2008	CAN / CSA- ISO 13485-2003, Quality System – Medical CMDCAS Devices ISO 13485: 2003	QSR, 21 CFR Part 820	MDD Council Dir.93/42/EEC)
7.4 Purchasing (title only) 7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product.	7.4 Purchasing (title only) 7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product.	820.50 (a, b) Purchasing controls	
7.5 Production and service provision (title only) 7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision 7.5.3 Identification and traceability 7.5.4 Customer property 7.5.5 Preservation of product	7.5 Production and service provision (title only) 7.5.1 Control of production and service provision 7.5.1.1 General requirements 7.5.1.2 Control of production and service provision-specific requirements 7.5.1.2.1 Cleanliness of product and contamination control 7.5.1.2.2 Installation activities 7.5.1.2.3 Servicing activities 7.5.1.3 Particular requirements for sterile medical devices 7.5.2 Validation of processes for production and service provision 7.5.2.1 General requirements 7.5.2.2 Particular requirements for sterile medical devices. 7.5.3 Identification and traceability 7.5.3.1 Identification 7.5.3.2 traceability 7.5.4 Customer property 7.5.5 Preservation of product	820.70 Production and process controls 820.160 Distribution 820.60 Identification 820.65 Traceability 820.80 (a, b) Receiving, in-process and finished device acceptance 820.200 Servicing 820.140, 150, Handling, Storage	Annex II, Section 3.2
7.6 Control of monitoring and measuring devices	7.6 Control of monitoring and measuring devices	820.72 Inspection, measuring and test equipment	

APPENDIX I – STANDARDS CORRELATION MATRIX

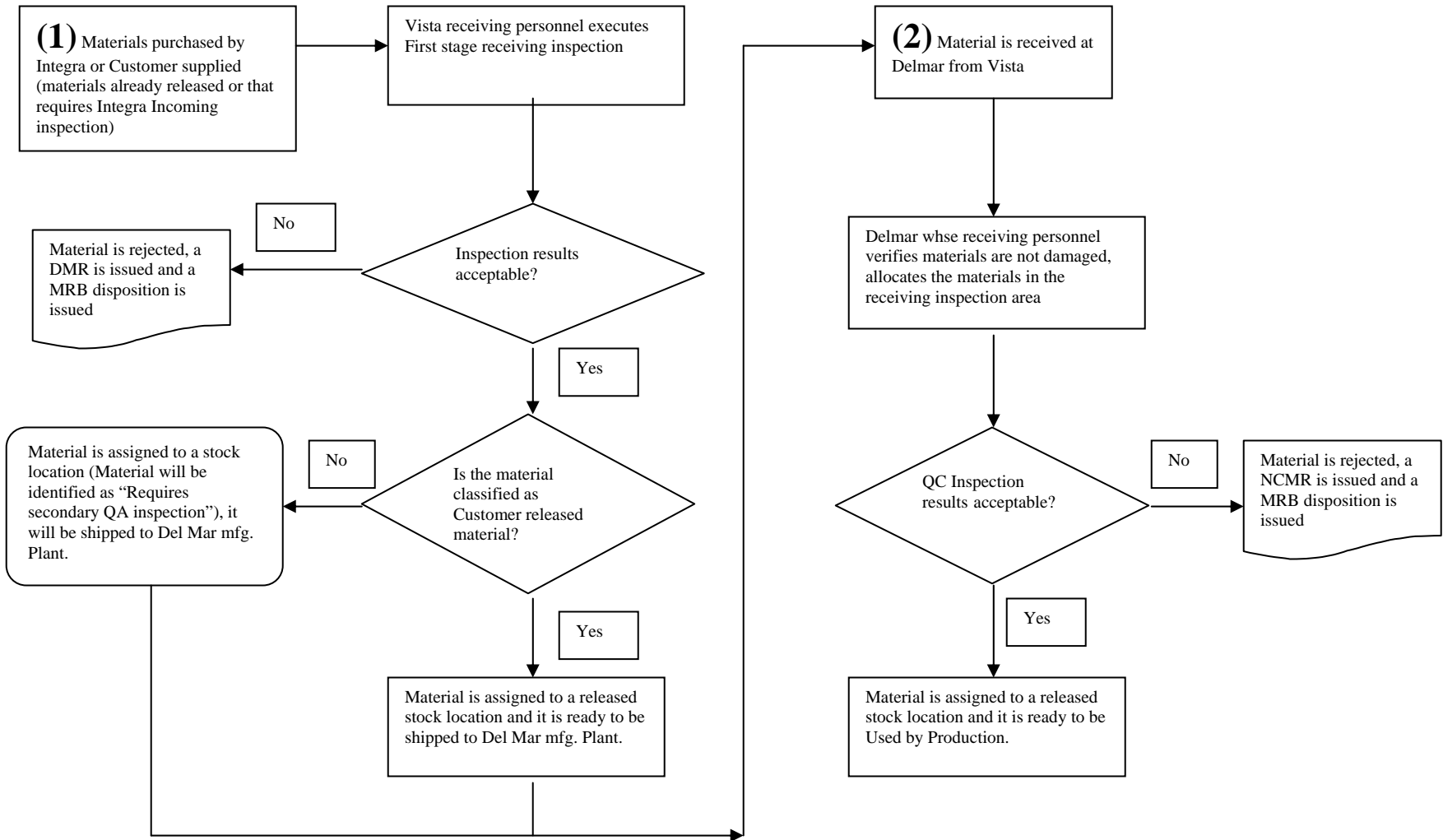
ISO 9001:2008	CAN / CSA- ISO 13485-2003, Quality System – Medical CMDCAS Devices ISO 13485: 2003	QSR, 21 CFR Part 820	MDD Council Dir.93/42/EEC)
8 Measurement, Analysis and improvement (title only)	8 Measurement, Analysis and improvement (title only)		
8.1 General	8.1 General		
8.2 Monitoring and measurement 8.2.1 Customer satisfaction 8.2.2 Internal Audit 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product	8.2 Monitoring and measurement 8.2.1 Feedback 8.2.2 Internal Audit 8.2.3 Monitoring and measurement of processes 8.2.4 Monitoring and measurement of product	820.22 Quality audits 820.250 Statistical techniques	
8.3 Control of Non-conforming product	8.3 Control of Non-conforming product	820.90 Control of non-conforming product	
8.4 Analysis of data	8.4 Analysis of data	820.250 Statistical techniques	
8.5 Improvement (title only) 8.5.1 Continual improvement 8.5.2 Corrective Action 8.5.3 Preventive action	8.5 Improvement (title only) 8.5.1 Continual improvement 8.5.2 Corrective Action 8.5.3 Preventive action	820.20 (c) Management review 820.100 Corrective and preventive action	Annex II, Section 3.1

APPENDIX II – Overall Process Flow



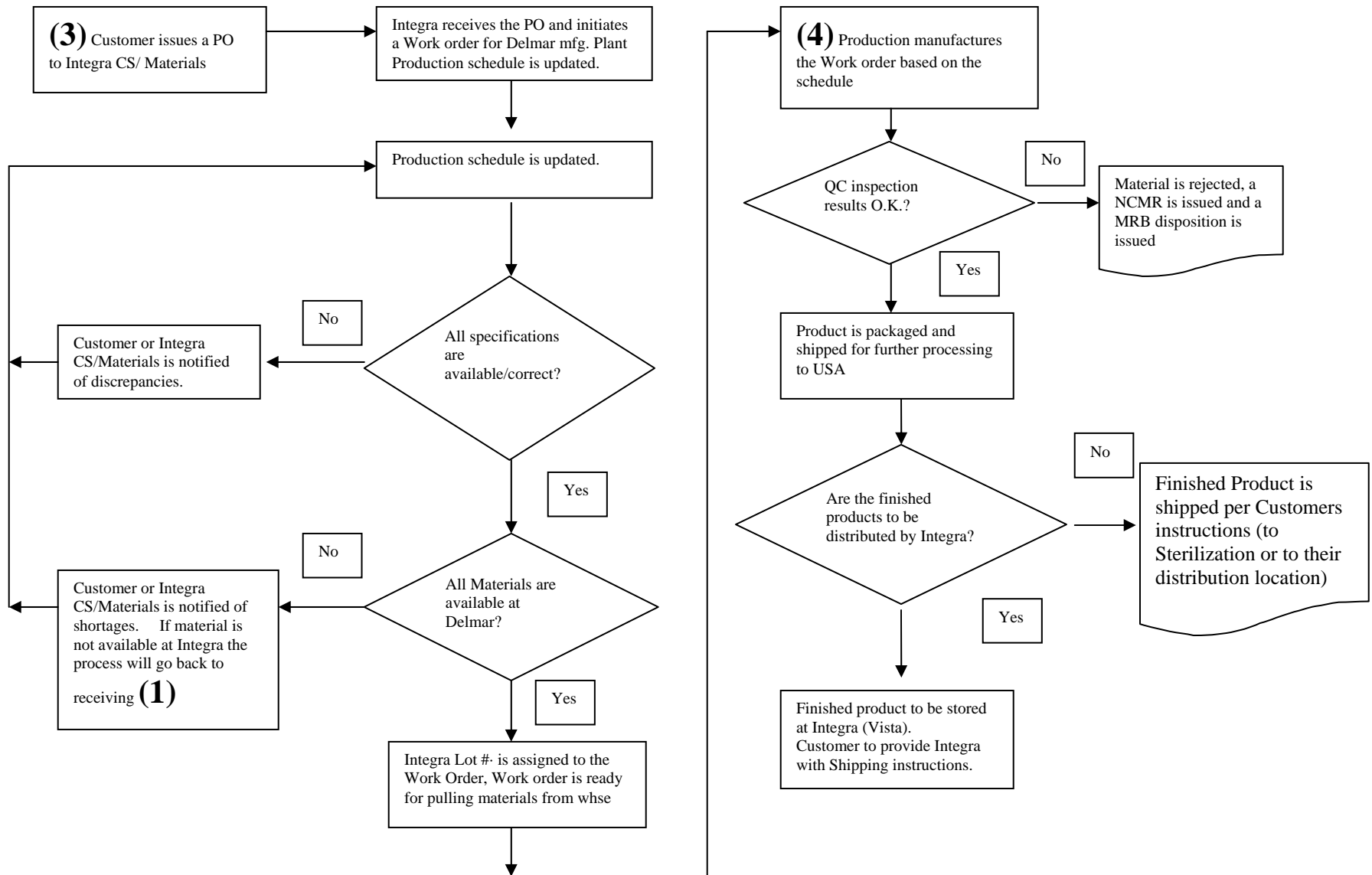
APPENDIX II – Overall Process Flow

Receiving USA/ Mexico



APPENDIX II – Overall Process Flow

Planning/Production/Shipping



APPENDIX III – ORGANIZATIONAL CHART

