



Policy Manual Index

Rev. 19, 07/30/09

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CERTIFICATION

DOCUMENT # POL-SI-001

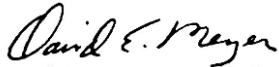
REV # 19

July 30, 2009

The CEO/President, Deputy CEO/President EMEAA and Corporate Vice President of Regulatory Affairs and Quality Assurance of Sterigenics International have endorsed and approved the Quality System described in these Quality Policies which hereby certifies that it meets the intent of:

North America (including NA Operations, SteriPro Labs and SteriPro Consulting): ISO 9001:2000, ISO 13485:2003, ISO 11137-1 & 11135-1 and the revisions thereto in effect on the date of their signatures.

EMEAA (including EMEAA operations and laboratories): ISO 9001:2000, ISO 13485:2003, EN ISO 11135-1, EN ISO 11137-1, EN ISO 17665-1 and the revisions thereto in effect on the date of their signatures.



CEO/President

05/07/09

Date



Deputy CEO/President

05/25/09

Date



Corporate Vice President RA/QA

05/07/09

Date

INTRODUCTION TO THE STERIGENICS
QUALITY ASSURANCE POLICY MANUAL
NORTH AMERICA, EMEAA AND LABORATORY

DOCUMENT # POL-SI-001

REVISION # 2

APRIL 30, 2005

The basic Sterigenics quality assurance program is described in the Quality Policies contained in this document. This manual defines senior management's quality assurance philosophy and operating policies. Responsibilities for their implementation and administration are described. The Quality Policies provide general requirements to assure criteria are met and consistent controls are exercised to maintain adherence to contractual and regulatory requirements.

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In order to provide consistent quality service to our customers, Sterigenics operates from a standardized global quality policy manual at all facilities included in the North America, EMEAA and Laboratory network. Quality system level procedures are standardized within each of these three groups, and in addition, procedures which control the technological process (Process Procedures) and Work Instructions are standardized within each technology (Gamma, Ebeam (Medical and Advanced Applications), EO, Laboratory) and business line, e.g., medical sterilization, food safety, advanced material ionization, laboratory network.

On April 30, 2005 this Quality Policy Manual was issued as revision (2) in order to reflect the change to combine the Quality Policy Manuals for North America, EMEAA, and the Laboratory into one Quality Policy Manual. The previous EMEAA Quality Policy Manual was EU-POL-SI-001 (Rev. 1), and the previous Laboratory Quality Policy Manual was POL-SI-002, (Rev. 1).

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QUALITY POLICY MANUAL

1.0 Scope (820.1)

Sterigenics North America, EMEAA and Laboratory, hereafter referred to as “the organization”, shall implement a quality management system, that defines the quality system, its implementation for the processing services, and demonstrates the capability to consistently provide conforming product. The quality system’s primary purpose is to achieve customer satisfaction through continual improvement and prevention of nonconformity.

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This quality manual defines the quality management system and its implementation for processing services provided by Sterigenics North America and EMEAA, and for laboratory services provided by the Laboratory. This system is structured to comply with the standards listed in Section 2.0 Normative References.

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1.1 Reduction in Scope

Sterigenics North America (Gamma, EO and E-Beam processing sites) and EMEAA (Gamma, EO and E-Beam processing sites and laboratories) do not provide design services, and therefore, ISO 9001:2000, and ISO 13485:2003, section 7.3, Design and Development, does not apply to these processing sites.

ISO 13485:2003, ISO 9001:2000, Section 7.3, Design and Development is only applicable to Sterigenics SteriPro and/or Analytical Laboratories.

The following sections (including all related sections) of the ISO 13485:2003 standard are considered as non-applicable to Sterigenics North America and EMEAA processing sites and laboratories:

- Section 7.5.1.2. “Control of Production and Service Provision – Specific Requirements.”
- Section 7.5.3.2.2. “Traceability: Particular requirements for active implantable medical devices and implantable medical devices.”

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2.0 Normative References

The organization's quality management system will comply with the most recent standards:

North America: ISO 9001:2000, *Quality Management Systems – Requirements*; ISO 13485:2003, *Medical Devices – Quality Management Systems*; ISO 11135-1, *Medical devices -- Validation and routine control of ethylene oxide sterilization*; ISO 11137-1, *Sterilization of health care products – Radiation*; 21 CFR part 820, *Quality System Regulation QSR Requirements for Medical Device Manufacturers*; and Japanese MHLW 169.

North America Laboratory: ISO 9001:2000, *Quality Management Systems – Requirements*; ISO 13485:2003, *Medical Devices – Quality Management Systems*; 21 CFR parts 820 and 58, *Quality System Regulation QSR Requirements for Medical Device Manufacturers and Good Laboratory Practice for Nonclinical Laboratory*; ISO 17025, *General requirements for the competence of testing and calibration laboratories*; ISO 11135-1, *Medical devices -- Validation and routine control of ethylene oxide sterilization*; ISO 11137-1, *Sterilization of health care products – Radiation*; and Japanese MHLW 169.

EMEA: ISO 9001:2000, *Quality Management Systems – Requirements*; ISO 13485:2003, *Medical Devices – Quality Management Systems*; EN ISO 11135-1, *Medical devices -- Validation and routine control of ethylene oxide sterilization*; EN ISO 11137-1, *Sterilization of health care products – Radiation*; EN ISO 17665-1, *Sterilization of health care products -- Moist heat*; and Japanese MHLW 169.

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Where other national standards or regulations require adherence, they too shall be applied, but only to the appropriate technology or facility. These standards may include, but are not limited to, 21 CFR part 820, EU GMP, ISO 17025, and Thai GMP (for Thailand).

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3.0 Terms and Definitions (820.3)

For the purpose of this quality manual the terms and definitions given in ISO 9001:2000 *Quality management systems – Fundamentals and vocabulary*, shall apply.

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4.0 Quality Management System Requirements (820.5)

4.1 General Requirements

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The organization shall establish a quality management system encompassing the requirements of Section 2.0 Normative References. The quality management system shall be implemented, maintained and improved by the organization. To implement the system the organization shall:

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- a. identify the processes needed for the quality management system and their application throughout the organization (see Attachment A)
- b. develop system level procedures that describe the activities required to implement the quality system;
- c. develop procedures that list the sequence and interactive nature of the process to ensure conformity of product;
- d. determine the criteria and methods and develop applicable work instructions required to ensure effective operation and control of processes;
- e. ensure that necessary information is available to support the operations and monitor processes;
- f. measure, monitor, analyze processes, and implement actions necessary to achieve planned results and continual improvement.

4.2 Documentation Requirements

4.2.1 General

Quality management documentation shall include, at a minimum:

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- a. documented statements of a quality policy and quality objectives;
- b. system procedures necessary to implement requirements of Section 2.0 Normative References;
- c. adequate work instructions and quality records to ensure effective operation and control of processes;
- d. documents needed to ensure the effective planning, operation, and control of process;
- e. any other documentation specified by national or regional regulations.

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The range and extent of quality system documentation shall be dependent on the size and type of processing/testing in the facility; complexity and interaction of the processes; methods used, and the skills and training of personnel.

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4.2.2. Quality Manual (820.20 e)

The Quality Manual shall contain:

- a. the scope of the quality management system, including details of and justification for any exclusion and/or non-application;
- b. the requirements and a description of the elements of the quality management system and their interaction;
- c. reference to the procedures established to implement the quality system (including a procedure which describes the structure of the documentation).

4.2.3 Control of Documents (820.40)

The organization shall establish and maintain system level procedures to control all documents and data that relate to the requirements of this Quality Management System. The procedures shall ensure that:

- a. documents are reviewed and approved for adequacy prior to release;
- b. documents are reviewed, updated as necessary and re-approved;
- c. relevant versions of documents are available at locations where activities essential to the effective functioning of the quality management system are performed;
- d. obsolete documents are removed from all points of issue and use, or otherwise controlled to prevent unintended use;
- e. any obsolete documents are retained for legal or knowledge-preservation purposes are suitably identified;
- f. records and documents shall be legible, readily identifiable, retrievable and in the form of hard copy or electronic media; documents of external origin shall be identified and recorded;
- g. a master list (e.g., index/date register) must identify the current revision level of documents to prevent the use of obsolete documents.

4.2.4 Control of Records (820.180)

- a. Quality records shall be controlled and maintained to demonstrate conformance to specified requirements and the effective operation of the quality management system.
- b. A system level procedure shall be established for identifying, collecting, indexing, accessing, filing, storing, maintaining, retaining, protecting and disposing of quality records.

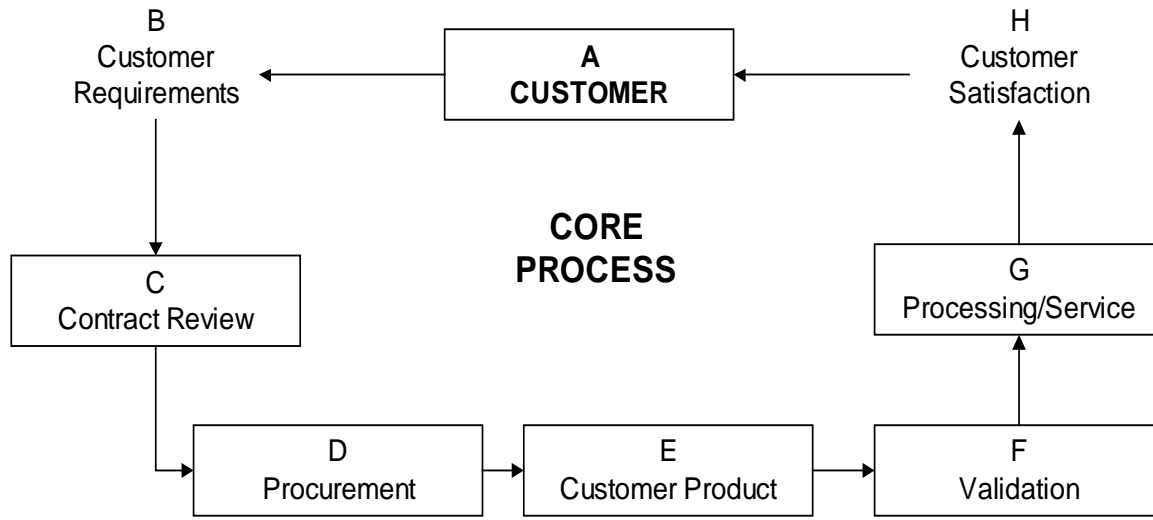
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- c. Where records are retained via electronic media or electronic records are signed via electronic signatures, the requirements defined in 21 CFR part 11 shall be followed, where applicable.

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ATTACHMENT A

Sterigenics Quality Management System Process



Management Supporting Processes

See applicable Appendix for Procedural Reference

Appendix A - North America, Denmark, Thailand & China

Appendix B - Laboratory

Appendix C - EMEA

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5.0 Management Responsibility (820.20)

5.1 Management Commitment

Senior management shall demonstrate its commitment to:

- a. creating and maintaining awareness of the importance to fulfill customer requirements, as well as regulatory and legal requirements, by ensuring policies for communication of customer requirements are established and implemented;
- b. establishing the quality policy, quality objectives and quality planning by developing, documenting, and ensuring communication of said policy, as well as achievement of objectives and plans;
- c. conducting management reviews at the senior management level and reviewing reports of management review submitted by facility personnel;
- d. ensuring the availability of resources.

5.2 Customer Focus

Senior management shall ensure that:

- a. customer needs and expectations are determined and converted into requirements with the aim of achieving customer confidence by establishing policies for customer contracts and communication of contractual requirements to appropriate personnel throughout the process to ensure adherence;
- b. customer requirements are fully understood and met by establishing policies for the identification, review, and communication of the customer requirements.

5.3 Quality Policy (820.20 a)

It is the responsibility of senior management to develop the organization's quality policy and ensure that:

- a. it is appropriate for the organization and our customers;
- b. resounds the commitment for meeting customer requirements;
- c. encourages continual improvement;
- d. provides a framework for establishing and reviewing quality objectives;
- e. is communicated, understood, and implemented throughout the organization;
- f. is reviewed for continuing suitability.

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The quality policy for the organization is defined below:

It is the policy of the organization to achieve customer satisfaction by meeting customer requirements the first time and every time. To each of us, the principle is straightforward:

DO THE JOB RIGHT, THE FIRST TIME AND EVERYTIME!

Organization Quality Mission:

- a. provide sterilization, ionization, irradiation services, and laboratory services that are consistently and reliably in compliance with the customer, company, and regulatory requirements;
- b. maintain a quality management system that provides the framework for achieving customer satisfaction, prevention of nonconformance, and continual improvement by applying a process-based approach throughout the organization.

5.4 Planning (820.20 d)

5.4.1 Quality Objectives

- a. The organization shall establish quality objectives at each relevant level and function within the organization.
- b. The Quality Objectives shall be measurable and consistent with the quality policy and the commitment to continual improvement.
- c. Quality objectives shall include those needed to meet requirements for services.

5.4.2 Quality Planning (820.20 d)

- a. Senior management shall ensure that planning is carried out to achieve quality objectives, the quality system management requirements, and continual improvement of the quality management system;
- b. Quality planning shall ensure that change is conducted in a manner that the integrity of the quality management system is maintained.

5.5 Responsibility, Authority, and Communication (820.20)

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The administration of the quality management system shall be defined as described herein.

5.5.1 Responsibility and Authority (820.20 b)

a. Organization

The organizational charts, defined at the end of this section (Attachments A thru F), define the relationship of the various functions within the organization and business lines.

A facility organizational chart defining the relationship and various functions of the facility's specific organization shall be developed and maintained at the facility. The organizational chart shall indicate the title, authority and interaction of personnel. Name of personnel are not required, and will be updated as needed listing a revision number and issue date.

The management shall ensure the independence and authority necessary to perform tasks which affect quality.

b. Facility and Departmental Managers

Each member of management is ultimately responsible for:

- i. implementing and communicating the quality policy and requirements of the quality management system throughout their respective departments;
- ii. assuring that requirements of the quality management system are available and followed by each employee;
- iii. ensuring that employees are provided with the proper training to perform the duties required of their position;
- iv. initiating action to prevent the occurrence of product nonconformance;
- v. initiating and providing solutions through designated channels.

c. Specific responsibilities of managers are to be documented in applicable job descriptions.

d. Quality Assurance Manager Authority

The Quality Assurance Manager is given the authority and

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responsibility to represent the facility/laboratory on all quality matters pertinent to the quality management system as established through customer and regulatory requirements and company quality policies and procedures. For this reason the Quality Assurance Manager, in addition to reporting directly to the General Manager or Director/General Manager, also reports, on a dotted line basis, to the applicable VP of Quality Assurance (North America or EMEAA).

Should a dispute occur between Operations, General Manager, Director/General Manager and the Quality Assurance Manager, in regard to the quality of a product, service or regulatory issue, the issue will be brought before the VP of Quality Assurance (North America or EMEAA) for resolution.

If the VP of Quality Assurance (North America or EMEAA) is unavailable for decision-making purposes, the President or the Vice President of Corporate Regulatory Affairs/Quality Assurance will resolve any decisions affecting quality.

5.5.2 Management Representative (820.20 b.3)

The Vice President of Quality Assurance (North America or EMEAA) is given the responsibility of Management Representative for the overall quality program at the corporate level for all business lines. The Vice President of Quality Assurance (North America or EMEAA) has the authority and the responsibility for ensuring that the requirements of the quality system are implemented and communicated to all business lines, reporting to senior management on the performance of the quality management system and any need for improvement, and ensuring the promotion and awareness of regulatory and customer requirements throughout the organization.

The Quality Assurance Manager is given the responsibility of Management Representative at the facility level. The Quality Assurance Manager has the authority and responsibility to:

- a. maintain compliance to the requirements established in the quality management system;
- b. ensure that quality system performance is evaluated and areas that need improvement are identified and reported to Senior management;
- c. ensure awareness of regulatory and customer requirements.

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5.5.3 Internal Communication

The organization shall establish and maintain procedures for internal communication between the various levels and functions regarding the quality management system and its effectiveness.

5.6 Management Review (820.20 c)

On an annual basis senior management, at the corporate level, shall review and evaluate the suitability, adequacy, and effectiveness of the quality management system, policy, and objectives, including the need for changes to said system.

An annual review and evaluation is also performed at the facility/laboratory level by local management. The results of this review will be utilized during the corporate review process.

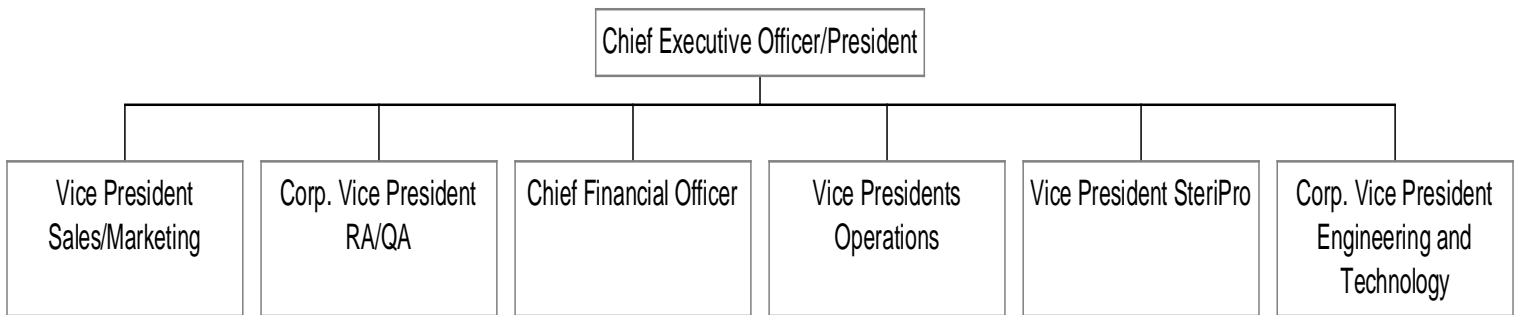
The review input shall consist of evaluations of current performance and improvement opportunities related to findings from internal, regulatory, and customer audits, customer feedback, process performance and conformance, preventive and corrective actions, market strategies, and information on new or revised regulatory requirements, follow-up from earlier management reviews, and recommendations for improvement.

The output of management review shall include actions related to improvement of the quality management system and its processes, improvement toward meeting customer requirements, and any revised or new regulatory requirements, and resources needed to achieve improvement.

The input and output of management review will be documented.

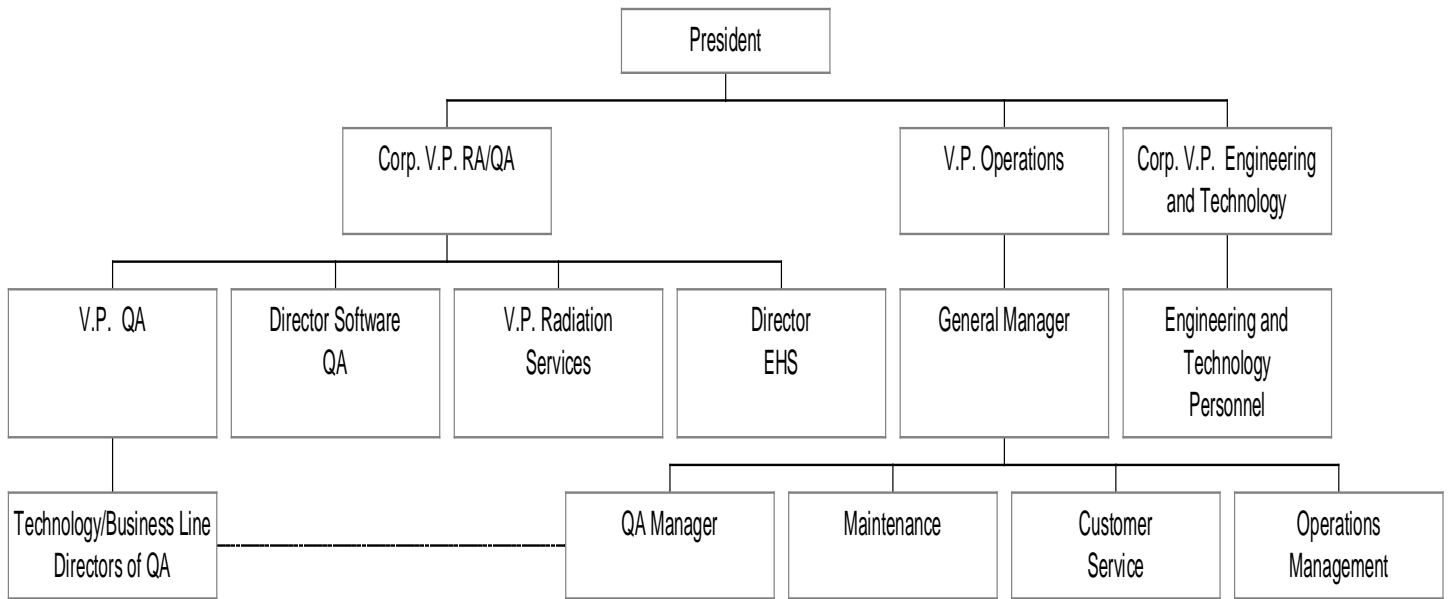
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Organizational Chart Sterigenics Senior Management Attachment A North America



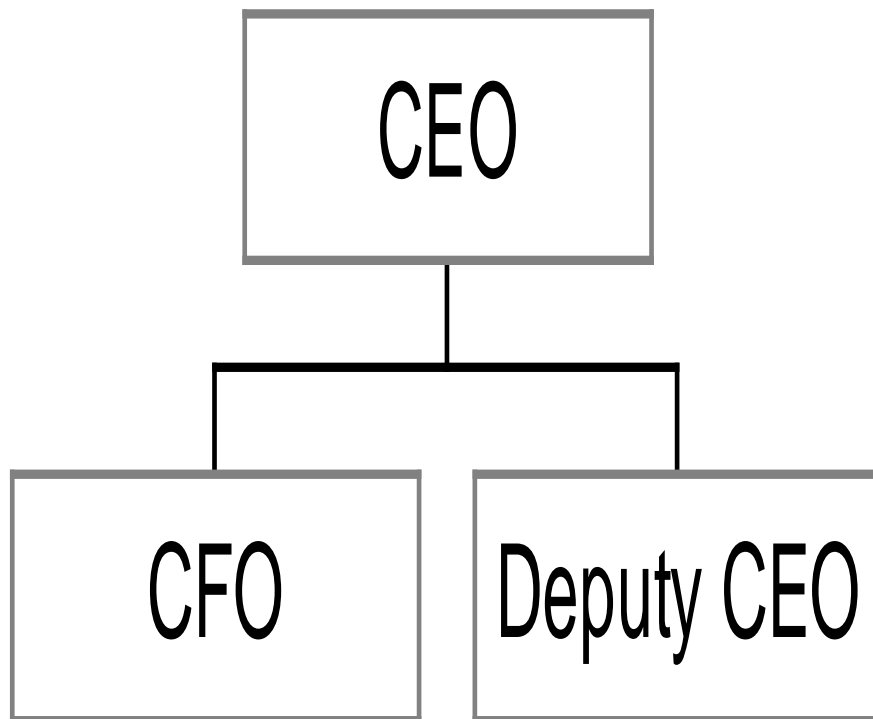
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Organization Chart Sterigenics Operations Attachment B North America



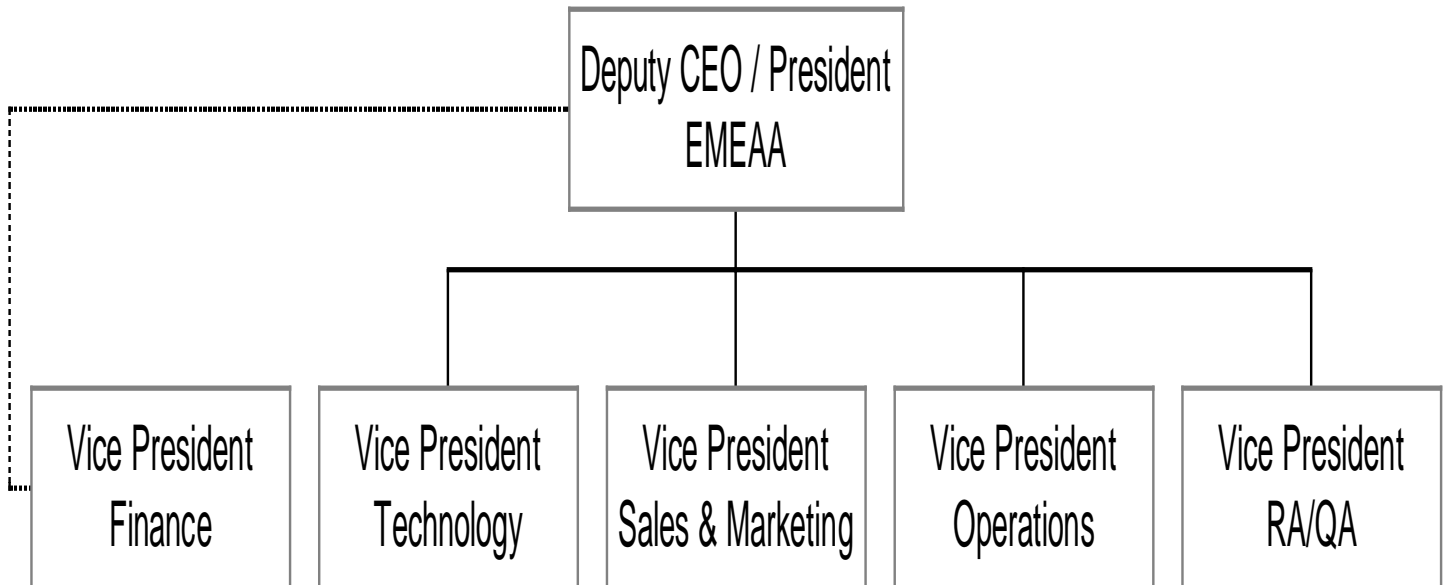
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Organizational Chart Sterigenics
Senior Executive Management
Attachment C
EMEA



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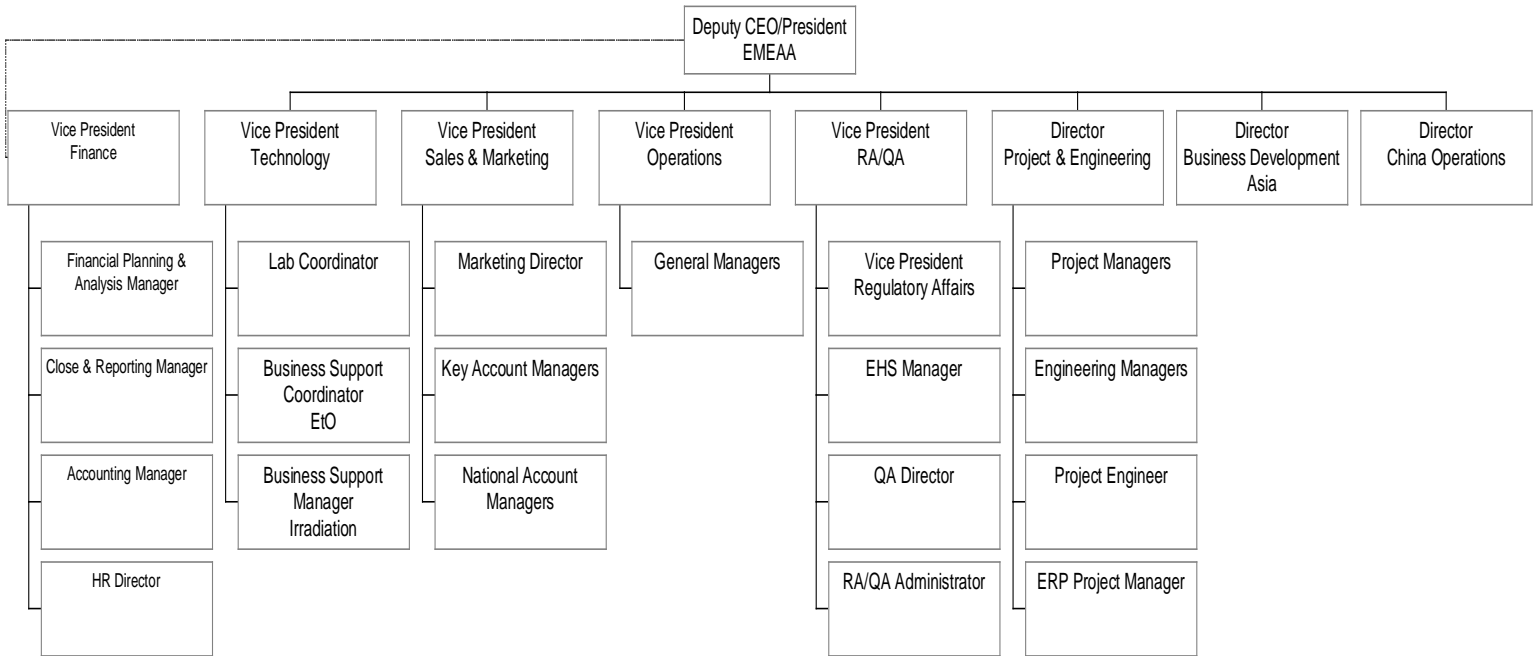
Organization Chart Sterigenics Senior Management Attachment D EMEA



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Organization Chart Sterigenics Operations Attachment E EMEA

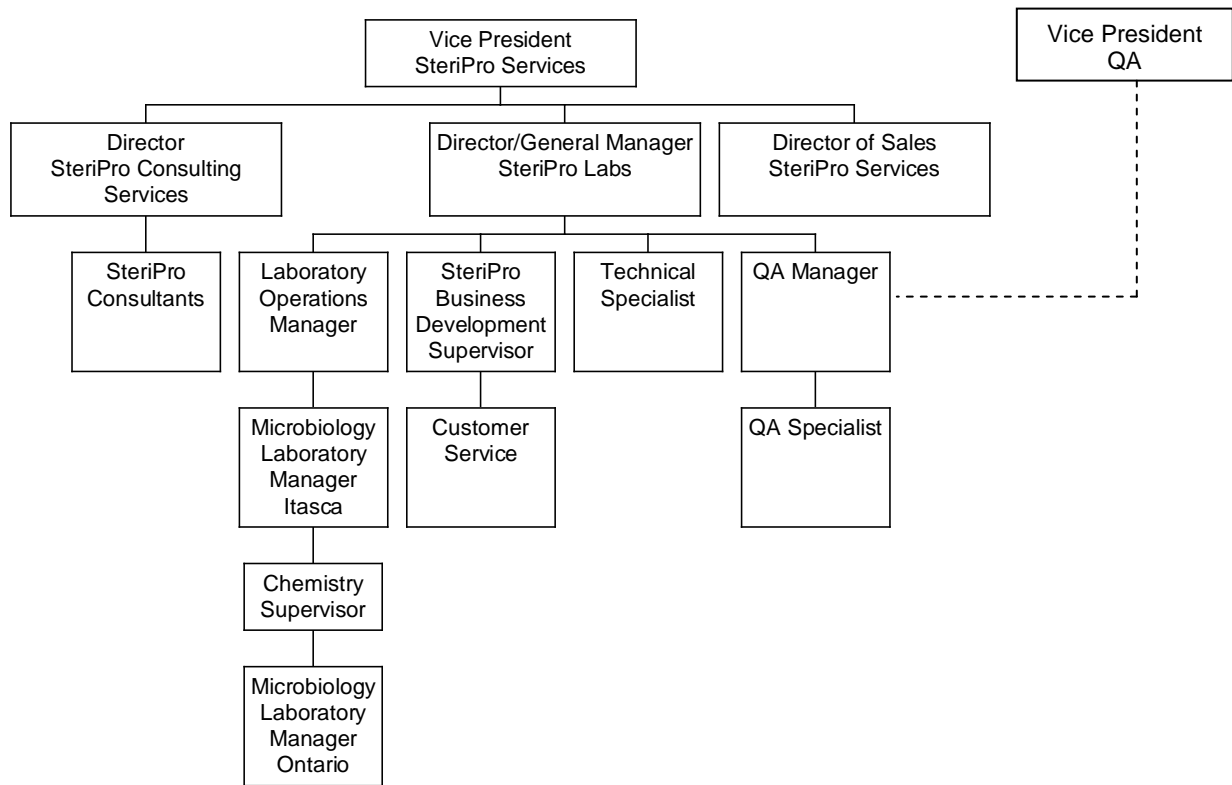
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STERIPRO LABS ORGANIZATIONAL CHART Attachment F



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6.0 Resource Management (820.20 b.2)

6.1 General Requirements

\$@ The company shall determine and provide in a timely manner, the resources needed to establish, implement, maintain and improve the quality management system and meet customer and regulatory requirements.

6.2 Human Resources (820.25)

6.2.1 Assignment of personnel (820.25 a)

The organization shall define the requirements of each position and assign personnel who are competent to perform the responsibilities of the quality management system based upon applicable education, training, skills and experience.

6.2.2 Training, Awareness and Competency (820.25 b)

The organization shall establish and maintain a quality system level procedure to:

- a. determine competency and training needs;
- b. provide training to address identified needs;
- c. evaluate the effectiveness of training;
- d. maintain appropriate records of education, training, skills, and experience;
- e. ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives and meeting customer requirements.

6.3 Infrastructure (Facilities) (820.70 f)

The organization shall determine and maintain the facilities needed to provide services that conform to customer requirements. The company shall provide and maintain the following:

- a. workspace and suitable building design to perform operations, prevent mix-ups and product damage;

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- b. processing and measurement equipment, hardware, and software;
- c. suitable maintenance and ongoing preventive maintenance of equipment and building;
- d. supporting services necessary to ensure conforming product.

6.4 Work environment (820.70 d)

The organization shall define and implement those human and physical factors needed to provide services that conform to customer and regulatory requirements. The company shall provide and maintain the following:

- a. adequate health, cleanliness, and safety practices;
- b. work instructions;
- c. adequate and comfortable working environment;
- d. suitable equipment.

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7.0 Product and/or Service Realization

7.1 Planning of Product Realization

The organization shall determine, plan and implement processes necessary to produce the required service. Planning of processes shall be consistent with the other requirements of the quality management system and shall be documented in a manner suitable for the operation. In planning the processes for realization of service, the following shall be determined, as appropriate:

- a. requirements for the product, test or study;
- b. the processes, documents, and resources to meet requirements;
- c. the required verification, validation, monitoring, inspection, and test activities, and criteria for product acceptance (where applicable);
- d. maintain as quality records the results of process control measures, to provide evidence of service conformance;
- e. The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained.

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7.2 Customer-Related Processes

7.2.1 Identification of Customer Requirements

The organization shall establish and document procedures for the review of customer requirements, i.e., contract review.

The contract review shall determine:

- a. customer product or service requirements, including the requirements for delivery, and post-delivery activities;
- b. requirements not specified by the customer but necessary for fitness of purpose;
- c. regulatory and legal requirements.
- d. any additional requirements determined by the organization

7.2.2 Review of Customer Requirements

The contract review is performed and the requirements agreed upon before the acceptance of the contract to assure the facility's capability

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to meet the contractual requirements. The contract review shall assure that:

- a. the requirements are clearly defined;
- b. where the customer provides no written requirements, the requirements are confirmed before acceptance;
- c. the requirements that differ from those previously expressed are resolved;
- d. the organization has the ability to meet the defined requirements.

Records shall be maintained of contract review and subsequent amendments.

The method for amending contracts and communicating the amendment to appropriate personnel shall be defined and documented.

7.2.3 Customer Communication

A customer communication system shall be established with the aim of meeting the customer requirements. This system shall define the communication requirements relating to:

- a. product and/or service information;
- b. inquiry and order handling, including amendments to orders;
- c. customer complaints and actions relating to nonconforming products or services;
- d. customer feedback relating to performance of product or service.

7.3 Design and Development

For the purposes of process development (specifically sterilization cycle design) which is performed as part of a consulting project, the SteriPro Analytical Laboratory shall; plan, manage, and document all activities related to the design and development process.

7.3.1 Design and development planning

As part of the planning process for design and development projects, laboratory management shall define:

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- a. The design and development project phases from initial customer contact through approval of the Final Report.
- b. The review, verification and validation that is appropriate for each phase of the project.
- c. The responsibilities and authorities of all parties involved in the project.

7.3.2 Design and development inputs

Inputs related to the process development project shall be determined, recorded, reviewed and maintained as part of the project file. These inputs shall include at a minimum

- a. customer requirements
- b. functional and performance requirements
- c. capability of the processing equipment
- d. applicable statutory and regulatory requirements
- e. where applicable, information derived from previous similar processes or related customer projects, and
- f. other requirements essential to design and development

7.3.3 Design and development outputs

The outputs of design and development shall be documented in the form of a Final Report that enables the verification against the design and development inputs and shall be approved by appropriate parties prior to implementation. The final report shall

- a. show that the input requirements for the design and development project have been met.
- b. provide appropriate information for successful execution of the designed process including process specifications and tolerances
- c. contain or reference the attainment of the project acceptance criteria
- d. specify the characteristics of the process that are essential for its safe and proper use.

7.3.4 Design and development review

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At suitable stages, systematic reviews involving appropriate individual(s) representing the various functions involved in the design and development project shall be conducted

- a. to evaluate the ability of the results of the design and development project to fulfill requirements and
- b. to identify an problems and propose necessary actions.

Results and necessary actions shall be documented and maintained as part of the design Project file.

7.3.5 Design and Development verification

Verification shall be performed through review of the Final Report to ensure that design and development outputs have satisfied and that the results of these reviews and any resulting actions have been documented.

7.3.6 Design and development validation

Validation activities shall be performed where required prior to delivery of the process to the customer or the processing facility and then at the facility prior to implementation of the process. Records and results of all validation activities shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation .

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts or products involved in the delivered process.

7.4 Purchasing (820.50)

7.4.1 Purchasing Process (820.50 a)

Methods, procedures and requirements shall be defined and implemented for purchase of critical supplies and services. The type

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and extent of control will be dependent upon the criticality of the purchased product or service.

Suppliers and consultants providing supplies or services which are critical to the maintenance of the quality management system or process controls must be evaluated to ensure the vendors ability to provide the specified supply or service required. Evaluation and, re-evaluation, and selection criteria shall be established in documented procedures.

Records shall be maintained to demonstrate the method used to qualify critical suppliers.

7.4.2 Purchasing Information (820.50 b)

- a. Methods, procedures and requirements shall be developed for the purchase of supplies or services and clearly communicated, defined, and understood by the vendors through the use of contracts, specifications, drawings or purchase orders.
- b. Purchasing documents shall include appropriate information to provide adequate qualification and approval of purchased products and services. Where appropriate, requirements for approval or qualification of product, procedures, processes, equipment, personnel, and quality management system will be defined.
- c. Purchasing documents are reviewed for accuracy and completeness prior to release by authorized individuals. Relevant purchasing information shall be maintained.

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7.4.3 Verification of Purchased Product/Service

The organization shall define and establish methods for the verification of purchased services and/or supplies for conformance to the specified requirements. The control of nonconforming materials or suppliers shall be documented in system level procedures.

Where the customer proposes that verification activities be performed at the supplier's premises, the verification requirements shall be specified in the purchasing documents. Records of the verification shall be maintained.

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7.5 Production and Service Provision

7.5.1 Control of Production (Operations)

The organization shall plan and control processing service operations, including those undertaken at initial delivery through processing and shipment of the product. This shall include:

- a. ensure the availability of specifications that define the characteristics of service required;
- b. ensure the use and maintenance of suitable equipment;
- c. ensure suitable working environments;
- d. ensure the availability and use of suitable measuring and monitoring equipment;
- e. ensure the implementation of suitable monitoring or verification activities;
- f. ensure suitable methods for release and delivery;
- \$ g. availability of documented procedures, documented requirements and work instructions;
- h. the implementation of defined operations for labeling and packaging, if applicable;
- i. The organization shall establish, verify, approve and maintain process history records (batch records), including process parameters for each sterilization batch. Sterilization records shall be traceable to each production batch of medical devices.

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7.5.2 Validation of Processes (820.75)

- a. Where the results of a process cannot be fully verified by inspection and test, the process shall be validated to demonstrate effectiveness and acceptability.
- \$ b. Procedures shall be established for validation, including software validation, to define and address:
 - @ i. the processes to be qualified prior to use;
 - ii. the use of qualified equipment and/or personnel;
 - iii. the specific procedures and necessary documents;
 - iv. re-validation requirements;
 - v. requirements for records.

7.5.3 Identification and Traceability (820.60, 820.65, 820.86)

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\$@ The organization shall establish documented procedures for the identification, traceability and status of customer product and controlled purchased supplies upon receipt and throughout all stages of production and shipment.

7.5.4 Customer Property

Customer property shall be identified, verified, stored, and maintained in a manner to prevent loss, mix-up, or damage. Any customer property that is identified as being lost, damaged, or otherwise unsuitable for use shall be recorded and reported to the customer. Customer property in the form of confidential information will remain confidential.

7.5.5 Preservation of Product (Handling, packaging, storage, preservation and delivery)(820.140, 820.150, 820.160)

The organization shall establish procedures to ensure that customer product is identified, stored, preserved, handled, and shipped in a manner that does not adversely affect conformity to customer requirements.

Product release and/or shipment shall not proceed until all specified activities have been satisfactorily completed, documented, and approved as being performed in accordance with the customer's requirements.

7.6 Control Of Measurement and Monitoring Devices; Inspection, Measuring, and Test Equipment (820.72 a, b)

\$@ The organization shall establish procedures to control, calibrate, and maintain measurement and monitoring equipment (device) used to demonstrate the conformance of the processes to specified requirements.

The organization shall:

- a. identify the measurements to be made, the accuracy required, and selection of the appropriate device, based upon the specified criteria;
- b. identify, calibrate, maintain, and adjust all inspection, measuring and test equipment, and devices that can affect process quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standard, where no

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- such standards exist, the basis used for calibration must be documented;
- c. establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
 - d. ensure devices are capable of and used in a manner that measurement uncertainty, including accuracy and precision, is known and consistent with the required measurement capability;
 - e. identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status;
 - f. record and maintain calibration activities as quality records;
 - g. evaluate and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration and take appropriate action where necessary;
 - h. ensure that the environmental conditions are suitable for calibrations, measurements, and tests being performed;
 - i. ensure that the handling, preservation, and storage of the devices are such that the devices are protected from damage and deterioration;
 - j. safeguard the devices from adjustments which would invalidate the calibration setting;
 - k. validate test hardware or test software used to verify the acceptability of processes.

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8.0 Measurement, Analysis, and Improvement

8.1 General

The organization shall plan and implement methods to measure, monitor and improve processes needed to:

- a. demonstrate conformity to customer or product;
- b. ensure conformity of the quality management system;
- c. continually improve the effectiveness of the quality management system.

The organization shall identify and use the appropriate statistical techniques.

8.2 Measurement and Monitoring

8.2.1 Measurement and Monitoring of Customer Satisfaction

The organization shall monitor information relating to customer perception as to whether the organization has fulfilled customer requirements. The methods used to measure this information shall be planned.

8.2.2 Internal Audit (820.22)

The organization shall perform internal quality assessments to assure effective implementation and compliance to the quality management system, regulations, and international standards, and the methods used to measure and monitor the quality management system.

Audits shall be scheduled at planned intervals, on the basis of the status and importance of the area, and results of previous audits.

Audits shall be conducted by qualified individuals that do not have direct responsibility for the location being audited.

The organization shall have a system level procedure for internal audits that includes:

- a. audit scope, methodology and frequency;
- b. responsibilities and requirements for conducting audits, recording and reporting results to management;
- c. timely corrective action on deficiencies found during the audit;

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- d. follow-up actions to verify the implementation of corrective action, and reporting the verification results.

8.2.3 Measurement and Monitoring of Process, Process Control (820.70)

The organization shall define and document methods for measurement and monitoring of processes necessary to ensure requirements are achieved and to demonstrate the process's continued ability to satisfy its intended purpose. Results shall be used to maintain and improve these processes.

The process will be implemented, measured and monitored for a state of control through the following:

- a. documented procedures and work instructions;
- b. approval of processes and process equipment;
- c. suitable equipment, designed in a manner to perform maintenance, adjustments, and cleaning;
- d. work performed by trained personnel and applicable criteria for workmanship defined;
- e. compliance with applicable national reference standards/codes, regulations, documented procedures and quality plans;
- f. monitoring, control, and inspection of the process through routine process data review and testing;
- g. suitable environment, facilities, and environmentally controlled conditions to perform quality operations;
- h. maintain procedures to prevent contamination of equipment or product by substances that could be reasonably expected to have adverse effect on product quality;
- i. adequate buildings of suitable design and sufficient space to perform necessary operations;
- j. ensure process integrity, prevent mixups, and preserve product condition;
- k. preventive maintenance and inspection of equipment;
- l. automated data processing systems and software, and any changes to said systems or software, used for production or quality system management, are validated for intended use;
- m. compliance to all quality management system and safety requirements;
- n. adequate health, cleanliness, and personnel practices.
- o. internal audits

All process inspections and testing shall be documented and retained as quality records.

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8.2.4 Measurement and Monitoring of Product and/or Service (820.80)

Procedures shall be established for receiving, in process, and final inspection activities as they relate to processing (Gamma, EO and Ebeam) and laboratory operations to assure that purchased supplies and services supplied to customers conform to specified acceptance criteria. Evidence of conformity to acceptance criteria shall be documented and records shall indicate the authority responsible for the release of the product or service.

Product release shall not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

8.3 Control of Nonconformity (820.90)

8.3.1 Nonconformity Control

The organization shall establish and maintain procedures to assure that product that does not conform to specified requirements is controlled to prevent unintended use or delivery. The procedures shall also define the responsibility and authority in dealing with nonconforming product.

Controls shall be documented in established procedures to provide for the identification, documentation, evaluation, segregation and disposition of nonconforming product.

8.3.2 Nonconformity Review and Disposition

Nonconformities shall be reviewed and action taken in accordance with documented procedures.

These nonconformities shall be handled in one or more of the following ways:

- \$@ a. corrected or adjusted to conform to requirements, or
- b. accepted by customer under concession, with or without correction or adjustment, or
- c. re-assigned for alternative valid application, or
- d. rejected as unsuitable.

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Corrections or adjustments of nonconforming product and/or service must be performed in accordance with written procedures and customer requirements.

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Records of nonconformities and subsequent actions taken, including concessions obtained, and identity of the person(s) authorizing the concession shall be maintained.

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When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data for Improvement

The organization shall establish and implement methods for the analysis of data in order to determine the effectiveness of the quality management system and identify areas of improvement. Applicable system level procedures shall identify the appropriate data for analysis from the quality records to evaluate quality performance trends. Results of said data analysis shall be submitted as input to management review.

The data shall be analyzed to provide information regarding:

- a. customer satisfaction through service quality trends regarding conformance to customer requirements;
- b. conformance to product requirements;
- c. process operation trends of performance to specifications;
- d. preventive actions;
- e. supplier performance.

8.5 Improvement (820.100)

8.5.1 Planning and Continual Improvement

The organization shall continually improve the quality management system by planning and managing necessary processes. Continual improvement of the quality management system will be promoted by the use of:

- a. the quality policy, objectives, internal audit results, analysis of data, corrective and preventive action;
- b. and management review.

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- c. Records of all customer complaint investigation shall be maintained.

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8.5.2 Corrective Action

The company shall establish a system for reducing or eliminating the cause of nonconformities. The system level procedure for the corrective action process shall address:

- a. identification of nonconformities (including customer complaints);
- b. determination of the causes of nonconformities;
- c. evaluation of the need for actions to ensure that nonconformities do not recur;
- d. implementation of actions determined necessary to ensure that nonconformities do not recur;
- \$@ e. recording the results of any investigation and of actions taken;
- f. ensuring that corrective actions taken are effective and recorded.

8.5.3 Preventive Action

The organization shall establish a system for eliminating the causes of potential nonconformities to prevent occurrence. Quality system records and results from the analysis of data shall be used as inputs for preventive action, as applicable. The system level procedure for the preventive action process shall address:

- a. identification of potential nonconformities;
- b. determination of the causes of the identified potential nonconformities and recording the results;
- c. determination of preventive action needed to eliminate causes of potential nonconformities;
- d. implementation of preventive action;
- \$ e. recording the results of any investigation and of actions taken;
- @ f. reviewing that preventive action taken is effective.

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9.0 Complaint Filing and Control (820.198)

The organization shall establish, implement and maintain a documented system level procedure for receiving, reviewing and evaluating all complaints.

System level procedures shall be established for the handling of complaints to include:

- a. complaints shall be processed in a consistent and timely manner;
- b. complaints, written or oral, shall be recorded upon receipt and tracked until completion;
- c. complaints will be evaluated to determine the necessity for an investigation, the results of the evaluation will be documented;
- d. complaints will be reviewed to determine if the occurrence warrants a report to the FDA under part 803, Medical Device Reporting, investigated and documented according to 21 CFR 820.198(d), or other local regulatory agencies, i.e., regulatory agencies outside of the United States. These records will be maintained in a separate portion of the complaint files;
- e. complaints involving the failure of a device due to the services provided by the organization shall be investigated and the results of the investigation shall be fully documented.

Complaint information shall be trended to ensure continued improvement of the process and service, and to measure customer satisfaction.

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10.0 Process/Test History Records (820.184)

The organization shall establish procedures that ensure Process History Records (PHR's) for each process run (Gamma, EO, EB, Steam) and Test History Records (THR's) for each laboratory test are maintained to demonstrate that the product was processed in accordance with the Customer Master Record or equivalent.

The Process History Record (Gamma, EO, EB, Steam) shall contain, at a minimum, the following information:

- a. the dates of processing;
- b. product ID and control numbers provided by the customer;
- c. the quantity processed;
- d. the quantity released;
- e. records which indicate the product has been processed in accordance with the specified requirements;
- f. the process run number.

The Test History Record for the laboratory shall contain, at a minimum, the following information:

- a. the dates of receipt, testing start, test completion;
- b. product ID and control numbers provided by the customer;
- c. the quantity tested or processed;
- d. the results of testing or processing;
- e. records which indicate the product has been processed or tested in accordance with the specified requirements;
- f. the process run or laboratory test number.

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11.0 Quality System Record (820.186)

The organization shall define and maintain a Quality System Record which shall include or refer to the location of the quality system components, i.e., procedures, work instructions, and quality records.

The QSR shall be issued and approved in accordance with organization's defined document control procedures.

Appendix A to
Document # POL-SI-001
Rev. #6, 01/30/08

Reference to Quality System Procedures
North America, Thailand, Denmark & China

QSP Doc #*	Title	ISO Reference	Process Model Reference
QSP001	Quality System Record & Components	4.2.1, 4.2.2	MS
QSP002	Quality Planning	5.4.1	A
QSP003	Internal Communication	5.5.1, 5.5.3	MS
QSP004	Document Control	4.2.3	MS
QSP005	Quality Records & Documentation Practices	4.2.4	MS
QSP006	Management Review	5.6	MS
QSP007	Training	6.2	MS
QSP008	Contract Review	5.2, 7.2	C
QSP009	Purchasing & Supplier Approval	7.4	D
QSP010	Product ID and Traceability	7.5.3, 7.5.4	E
QSP011	Software Validation	7.5.2	F
\$ QSP012	Internal Audit (EU-QSP012: Audits)	8.1, 8.2.2, 8.2.3	MS
@ QSP013	Control of Nonconformity & Deviation (EU-QSP013: Deficiency Handling)	8.3	MS
QSP014	Customer Complaints	7.2.3	MS
QSP015	Medical Device Reporting Regulation	n/a	MS
QSP016	Corrective & Preventive Action	8.1, 8.5	G
QSP017	Data Analysis for Improvement	8.1, 8.2.1, 8.4	MS
QSP018	Facility & Customer Master Records	7.1	C
QSP019	Personnel Hygiene	6.4	MS
QSP020	Building Security & Equipment	6.3, 6.4	MS
QSP021	Process Equipment Maintenance & Changes	7.5.1 (c)	G
QSP022	Preservation of Product	7.5.4, 7.5.5	E
QSP023	Measurement & Monitoring of Product and/or Services	8.2.3, 8.2.4	MS
\$ QSP024	Risk Management	7.1	MS
@ EU-QSP025	QOS	8.5.1	MS

Additional cross references found in applicable Process Procedures (XXXX = MDGA, MDEO, MTEB, FSGA, MDEB)

PP Doc #*	Title	ISO Reference	Process Model Reference
\$ PP-XXXX-001	Process History Record	7.1	C
PP-XXXX-007	Cleaning & Pest Control	6.4	MS
PP-XXXX-008	Process Controls	7.5.1, 7.5.2	G/F
PP-XXXX-010	Environmental Health & Safety	6.4	MS
@ PP-XXXX-012	Measurement Equipment	7.6	G

Process Model Key:

MS = Management Support
A = Customer
B = Customer Requirements
C = Contract Review
D = Procurement
E = Customer Product
F = Validation
G = Processing/Serviceing
H = Customer Satisfaction

* For Denmark and China documents the prefix "EU" is written in front of the document number.

Appendix B to
Document # POL-SI-001
Rev. 0, 04/30/05

Reference to Quality System Procedures
Laboratory

QSP Doc #	Title	ISO Reference	Process Model Reference
LB-QSP001	Quality System Records and Components	4.2.1, 4.2.2	MS
LB-QSP002	Quality Planning Lab	5.4.1	A
LB-QSP003	Internal Communications	5.5.1, 5.5.3	MS
LB-QSP004	Document Control	4.2.3	MS
LB-QSP005	Quality Records & Documentation Practices	4.2.4	MS
LB-QSP006	Management Review	5.6	MS
LB-QSP007	Training	6.2	MS
LB-QSP008	Contract Review	5.2, 7.2	C
LB-QSP009	Purchasing and Supplier Approval	7.4	D
LB-QSP0010	Product ID and Traceability	7.5.3, 7.5.4	E
LB-QSP0011	Software Validation	7.5.2	F
LB-QSP0012	Internal Audit	8.1, 8.2.2, 8.2.3	MS
LB-QSP0013	Control of Nonconformity and Deviation	8.3	MS
LB-QSP0014	Customer Complaints	7.2.3	MS
LB-QSP0015	Medical Device Reporting Regulation	Na	MS
LB-QSP0016	Corrective and Preventive Action	8.1, 8.5	G
LB-QSP0017	Data Analysis for Improvement	8.1, 8.2.1, 8.4	MS
LB-QSP0018	Facility and Customer Master Records	7.1	C
LB-QSP0019	Personnel Hygiene	6.4	MS
LB-QSP0020	Building Security and Equipment	6.3, 6.4	MS
LB-QSP0021	Process Equipment Maintenance and Changes	7.5.1 (c)	G
LB-QSP0022	Preservation of Product	7.5.4, 7.5.5	E
LB-QSP0023	Measuring and Monitoring of Product and/or Services	8.2.3, 8.2.4	MS
LB-QSP0024	Sterilization Design Control	na	

Additional cross references found in applicable Process Procedures

PP Doc #	Title	ISO Reference	Process Model Reference
PP-LB-001	Device Testing History Record	7.1	C
PP-LB-007	Cleaning and Pest Control	6.4	MS
PP-LB-008	Laboratory Process Control Requirements	7.5.1, 7.5.2	G/F
PP-LB-010	Environmental Health and Safety	6.4	MS
PP-LB-012	Laboratory Measurement Equipment	7.6	G

Process Model Key:

MS = Management Support	E = Customer Product
A = Customer	F = Validation
B = Customer Requirements	G = Processing/Servicing
C = Contract Review	H = Customer Satisfaction
D = Procurement	

Appendix C to
Document # POL-SI-001
Rev. #2, 01/30/08

Reference to Quality System Procedures
EMEA

SP Doc #	Title	ISO Reference	Process Model Reference
00-ISP-MA-MIS-001	Internal Communication	5.5.1, 5.5.3	MS
00-ISP-MA-MIS-002	Quality Planning	5.4.1	B
00-ISP-MA-MIS-003	Management Review	5.6	MS
00-ISP-QA-ADM-001	Document Control	4.2.3	MS
00-ISP-QA-ADM-002	Quality Records	4.2.4	MS
00-ISP-QA-ADM-004	Documentation Structure	4.2	MS
\$@ 00-ISP-QA-AUD-001	Audits	8.1, 8.2.2, 8.2.3	MS
00-ISP-QA-DEF-001	Deficiency Handling	8.3	MS
00-ISP-QA-DEF-002	Corrective & Preventive Action	8.1, 8.5	G/MS
00-ISP-QA-DEF-003	Customer Complaints	7.2.3	H
00-ISP-QA-DEF-004	Medical Device Reporting	n/a	H
00-ISP-QA-IMP-001	Data Analysis for Improvement	8.1, 8.2, 8.4	MS
00-ISP-QA-IMP-002	QOS	8.1, 8.2.1, 8.4	MS
00-ISP-MA-TRN-001	Human Resources	6.2	MS
00-ISP-FI-MIS-001	Purchasing and Supplier Approval	7.4	D
00-ISP-IS-MIS-001	Software Validation	7.5.2	F
00-ISP-OP-MIS-001	Personnel Hygiene	6.4	MS
00-ISP-MA-JOB-001	Job Descriptions	6.2	MS
00-ISP-OP-VAL-001	Generic Validation Policy	7.5.2	F
00-ISP-QA-DEF-005	Risk Management	7.1	MS

Process Model Key:

MS = Management Support
A = Customer
B = Customer Requirements
C = Contract Review
D = Procurement
E = Customer Product
F = Validation
G = Processing/Serviceing
H = Customer Satisfaction