



MEDICAL TECHNOLOGIES LTD

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# CMT Quality Manual

**CMT Company Policy No. 1.2**

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# 1. Introduction & Scope

## 1.1 General

This Quality Manual specifies requirements for a quality management system by which CMT:

- a) Demonstrates its ability to consistently provide product that meets customer and applicable regulation requirements, and
- b) Enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulation requirements.

### Note:

In this Quality Manual, the term “product” applies to Medical Devices or services, intended for, or required by, a customer.

## 1.2 Application

All requirements of this Quality Manual are generic and are intended to be applicable to all CMT's activities, regardless of type or size of the product provided.

## 1.3 Company Profile

Established in 1984, CMT Medical Technologies Ltd. is an Israeli company which designs, develops, manufactures and markets medical digital diagnostic image processing systems. CMT's proprietary software and hardware allows storing, view and process X-ray images in a high quality, high-resolution digital form (Filmless). The systems are used in medical diagnostic imaging applications and provide real-time acquisition and display of X-ray images, allowing physicians to monitor critical procedures and make diagnosis.

Due to their flexibility and ability to communicate with various Dicom servers, CMT's products may be easily integrated into different kinds of X-ray rooms, including the most sophisticated ones.

Most of CMT's employees are highly skilled scientists, engineers and technicians. About 40% of the employees are employed in the R&D department.

CMT is Located in the Advanced Technology Center in Haifa, Israel.

## **2. Normative (Reference standards, Directives and Regulations)**

This Quality Manual follows the structure of the international standard ISO 9001:2000(E). However CMT has established and maintains documented files of procedures and work instructions that also meet the requirements of each element (when applicable) of the requirements of the ISO 13485 & EN 46001 for quality of Medical Devices, of the FDA Quality System Requirements (QSR) and of the MDD 93/42 EEC regulations and directives for Medical Devices.

From hereafter the term International Quality Standards will be used to describe ALL the above requirements.

### Note:

Since ISO 13485 & EN 46001 structure is based on the 1994 revision of the ISO 9001, a look-up table is attached to this Manual as Appendix B. It defines the relationship between the requirements of the two versions of the ISO 9001 standards.

The list of the International standards, applicable to CMT activities and products is attached to this manual as Appendix A.

## **3. Terms and Definitions.**

For the purposes of this Quality Manual, the terms and definitions given in ISO 9000 and in the 21 CFR 820.3, apply.

## **4. Quality Management System**

### **4.1 General requirements**

CMT has established, documented, implemented and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of this Quality Manual. Accordingly, CMT:

- a) Identifies the processes needed for the quality management system and their application throughout CMT activities.
- b) Determines the sequence and interaction of these processes.
- c) Determines criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.

- e) Monitors, measures and analyzes these processes.
- f) Implements actions necessary to achieve planned result and continual improvement of these processes.
- g) Maintains files containing documents (Device Master Record – DMR) defining the product specifications and requirements for complete manufacturing, installation and servicing.

These processes are managed by CMT in accordance with the requirements of this Quality Manual including the file of procedures, work instructions and forms. For Details refer to CMT documented procedures 2.1 and 2.2.

Where CMT chooses to outsource any process that affects product conformity with these requirements, CMT shall ensure control over such processes. The control of such outsourced processes are identified within this quality management system.

Note:

Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement.

## **4.2 Documentation Requirements**

### **4.2.1 General**

CMT quality management system documentation include:

- a) Documented statements of CMT quality policy and quality objectives (see par. 5.3, 5.4.1 below)
- b) This quality manual,
- c) Documented procedures required by Regulation and International Standards (see par. 2 above).
- d) Documents needed by CMT to ensure the effective planning, operation and control of its processes.
- e) Records required by this Quality Manual (see par. 4.2.4).

Notes:

- 1) Where the term “documented procedure” appears within this Quality Manual, it means that the procedure has been established, documented, implemented and maintained.
- 2) CMT documentation can be in any form or type of medium.

## 4.2.2 Quality Manual

CMT has established and maintains this quality manual that includes:

- a) The scope of the quality management system.
- b) Reference to the documented procedures established for the quality management system.
- c) A description of the interaction between the processes of quality management system.

## 4.2.3 Control of Documents

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

CMT documented procedure 2.14 has been established to define the controls needed:

- a) To approve documents for adequacy prior to issue.
- b) To review and update as necessary and re-approve documents.
- c) To ensure that changes and the current revision status of documents are identified.
- d) To ensure that relevant versions of applicable documents are available at points of use.
- e) To ensure that documents remain legible and readily identifiable.
- f) To ensure that documents of external origin are identified and their distribution controlled.
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

## 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 CMT quality management system. Records shall remain legible, readily identifiable and retrievable. CMT documented procedure 2.28 has been established to define the controls needed for the identification, storage, protection retrieval, retention time and disposition of records.

#### **4.2.5 The Commitment of Company Employees to Quality:**

- a) Every employee is responsible for the quality of his / her work or task.
- b) Every employee should initiate corrective actions and contribute, to the best of his / her ability, to the general effort for quality improvements.
- c) Every employee should work according to the company procedures, work instructions and official documentation of the company.
- d) Every employee should consult with his / her manager regarding professional issues.
- e) Every employee should carry out self-examination as to his / her own quality of work, before passing on the product to the next step in the production line.

#### **4.2.6 Changes in the Quality System**

- a) Changes in the global quality system of CMT can be divided to the following four categories:
  - 1) Related to the manufactured products.
  - 2) Related to production process.
  - 3) Related to the quality system.
  - 4) Related to CMT declarations.
- b) It is essential to distinguish between two types of changes:
  - 1) Major change.
  - 2) Minor change.
- c) According to the MDD (Medical Devices Directive) major changes need approval by the Notified Body before application in the Quality System. Therefore the Notified Body will only be informed about major changes, which have influence on the product and / or the production process.
- d) In case of major changes / modifications the Notified Body will be informed by CMT on the following issues:
  - 1) What are the changes?
  - 2) What is the reason for the changes?
  - 3) What measures were taken by CMT to assure that CMT is still in compliance with the requirements of the MDD?

- e) When a change is related to the device the following issues are to be observed:
  - 1) Has the intended purpose been changed?
  - 2) Has the labeling been changed?
  - 3) Has the design been changed?
  - 4) Have the materials / components been changed?
  - 5) What is the impact on the risk analysis?
  - 6) What is the impact on the essential requirements?
  - 7) Is the evidence that the product fulfills the safety requirements and / or the performance still sufficient?
- f) When a change is related to the production process the following issues are to be observed:
  - 1) What is the impact on product itself?
  - 2) How is the change validated and what are the results of this validation?
- g) When a change is related to the Quality System the following issues are to be observed:
  - 1) What is the impact on the primary processes?
  - 2) In that case what is the impact on the product?
  - 3) What is the impact on the MDD regulations?
  - 4) Is the Quality System still in compliance with the applied standards?
- h) Update of MDD declaration must always be reported to the Notified Body.

## **5. Management Responsibility**

### **5.1 Management Commitment**

CMT top management is commitment to the development and implementation of the quality management system and continually improving its effectiveness. It provides evidence to its commitment by:

- a) Communicating to the whole organization the importance of meeting customer as well as statutory and regulatory requirements.
- b) The quality policy stated in this Quality Manual.
- c) Ensuring that quality objectives are established.

- d) Conducting management reviews.
- e) Ensuring the availability of resources.

## 5.2 Customer Focus

CMT top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. The method in which CMT focuses on customer needs is described in details in CMT procedures and work instructions (see also 7.2.1 and 8.2.1).

## 5.3 Quality policy

CMT top management with executive responsibility has defined and documented the following quality policy.

The Company shall focus on customer requirements and shall ensure that customer expectations and needs will be met by continually improve the effectiveness of the quality management system by achieving the following quality objectives:

- a) To honestly market high quality medical devices.
- b) To comply with regulatory requirements and to assure the supply of safe and effective equipment.
- c) To deliver reliable products on time.
- d) To support and train its customers.
- e) To assure continuous reliable operation of its products by proper ongoing support of the maintenance and service of the products.
- f) To upgrade its products and provide continuous application support ensure long-range effective operation of its products.

The Company ensures that the above policy is communicated and well understood to its employees. This policy shall be reviewed for continuing suitability during CMT management reviews.

## 5.4 Planning

### 5.4.1 Quality Objectives.

CMT top management ensures, by maintaining a quality objectives plan, that the objectives, including those needed to meet requirements for product (see par. 7.1.a), are established at relevant functions and levels within CMT. The quality objectives shall be measurable and consistent with the quality policy. This quality objectives plan and its fulfillment shall be reviewed for continuing suitability during CMT management reviews.

### 5.4.2 Quality Management System Planning.

Planning of Marketing, Design, Design Transfer, Manufacturing, and Service processes, is an integral part of CMT Quality Management System.

The following pages schematically present CMT Quality Plans.

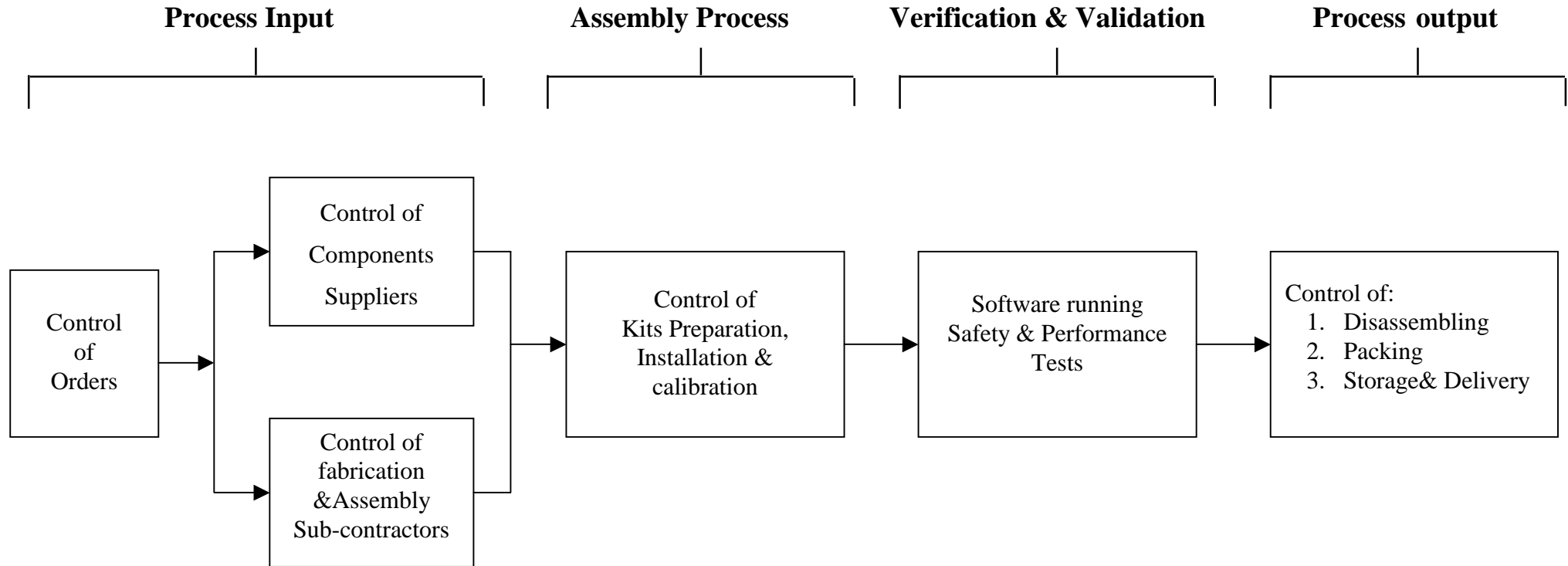
#### Practices:

Whenever possible the quality activities that are defined in the following flows will be executed by trained Engineering and Production employees rather than by QC employees. Whenever possible quality will be ensured by process control rather than by QC tests.

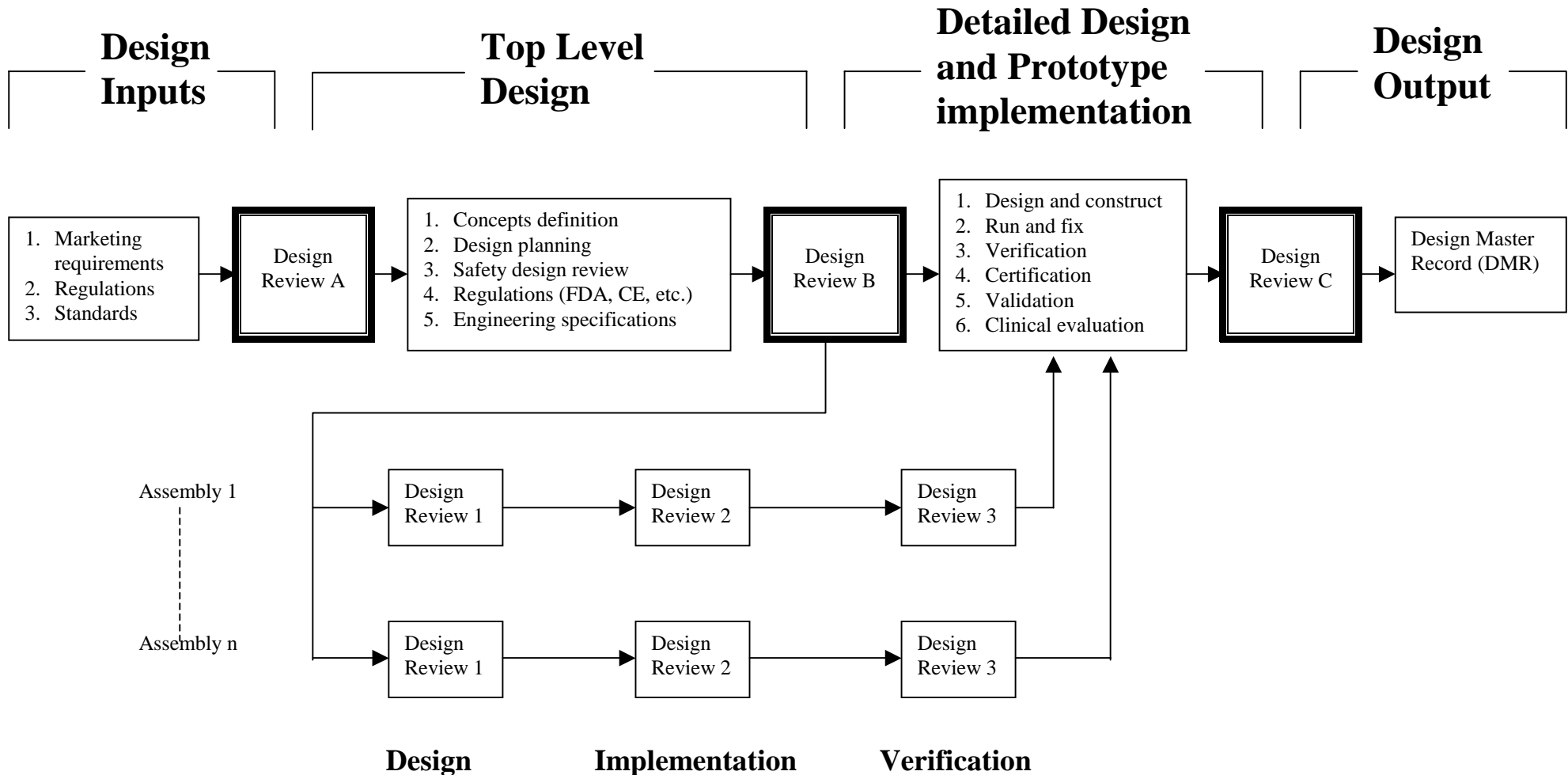
CMT top management reviews the company quality management system and ensures that:

- a) Its planning is carried out to meet the requirements given in par. 4.1, as well as the quality objectives.
- b) Its integrity is maintained when changes to this system are planned and implemented.

# Manufacturing Quality Plan

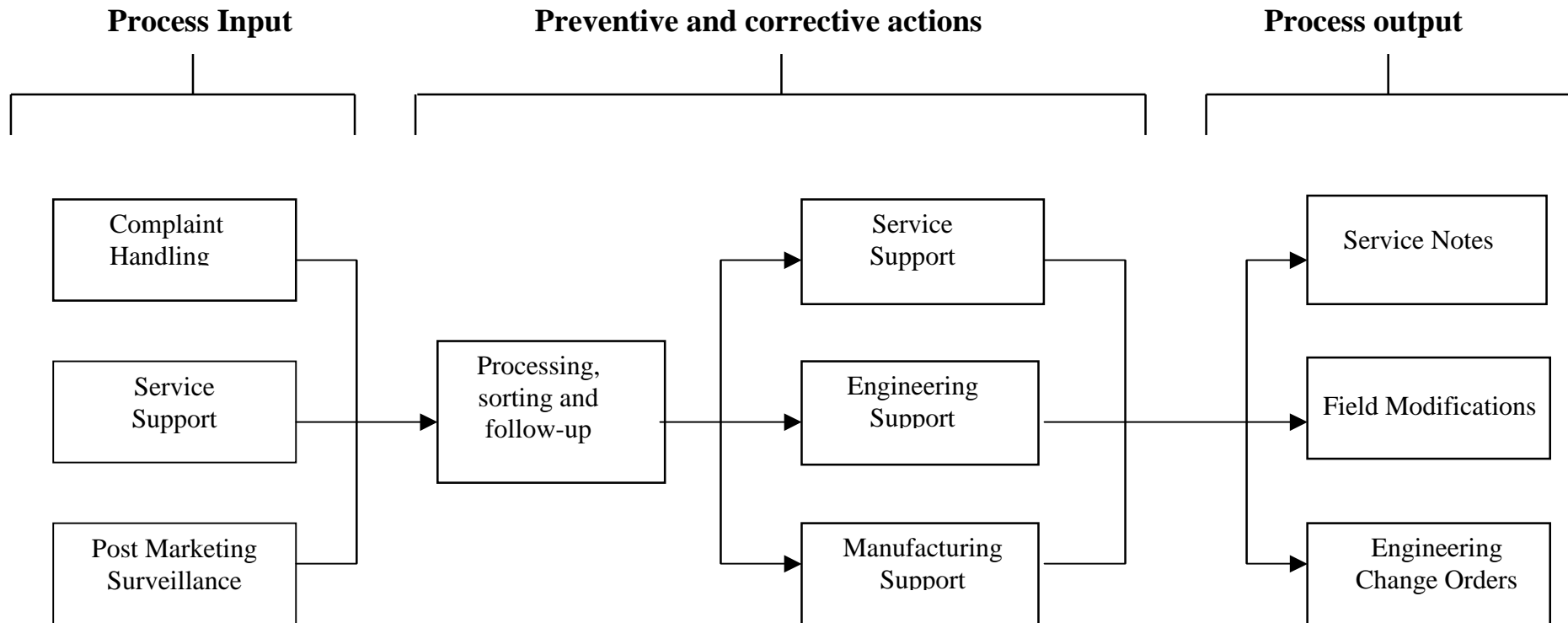


# Design Quality Plan



# Service Quality Plan

(Customer support & satisfaction)



## **5.5 Responsibility, Authority and Communication**

### **5.5.1 Responsibility and Authority.**

CMT has established and maintains an organizational structure that ensures that the devices are designed and produced in accordance of the International Quality Standards and regulatory requirements. The responsibilities and authorities of personnel, who manage, perform and verify work, which affects quality, is defined in detail and documented in par. 10.

CMT communicates, within the organization, the company responsibilities and authorities by (but not limited to) this Quality Manual.

The responsibility of the personnel who need the organizational freedom, independence and authority for Quality Assurance activities is defined in the following (next page) Responsibility - Quality Matrix.

Should any member of the management be unable to carry out his or her duties, then that person is required to inform CMT president in writing. CMT president will take all necessary actions to resolve the situation.

### Responsibility - Quality Matrix

No.	Subject	Quality Mgr.	R&D Mgr.	Operation Mgr.	
				Manufacturing	Customer Support
1.	Management Responsibility	✓			
2.	Quality System	✓			
3.	Contract Review	✓			
4.	Design Control		✓		
5.	Document and Data Control		✓	✓	✓
6.	Purchasing			✓	
7.	Control of Client Supplied Products			✓	
8.	Product Identification & Traceability			✓	✓
9.	Process Control			✓	
10.	Inspection & Testing			✓	
11.	Control of Inspection, Measuring & Testing Equipment		✓	✓	
12.	Inspection & Test Status			✓	
13.	Control of Non-Conforming Products			✓	✓
14.	Corrective and Preventive Action	✓	✓	✓	✓
15.	Handling Storage Packaging & Delivery			✓	
16.	Quality Records	✓	✓	✓	✓
17.	Internal Quality Audits	✓	✓	✓	✓
18.	Training	✓	✓	✓	✓
19.	Servicing				✓
20.	Statistical Techniques	✓		✓	✓

### **5.5.2 Management representative.**

CMT top management has appointed the Quality Manager as member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement.
- c) Ensuring the promotion of awareness of customer requirements throughout CMT organization.

Note:

The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

### **5.5.3 Internal communication**

CMT top management ensures that appropriate communication processes are established within CMT organization and that communication takes place regarding the effectiveness of the quality management system. The method in which CMT ensures the above includes routine management meetings and reviews. Each Management member is responsible to communicate to his/her subordinates regarding the effectiveness of the quality management system

## **5.6 Management review**

### **5.6.1 General**

CMT top management review CMT's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The method in which CMT review its quality management system is defined in CMT documented procedure 2.6. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained (see par. 4.2.4).

## 5.6.2 Review input

The input to management review includes, among others, information on the followings:

- a) Results of audits.
- b) Customer feedback.
- c) Process performance and product conformity.
- d) Status of preventive and corrective actions.
- e) Follow-up actions from previous management reviews.
- f) Changes that could affect the quality management system.
- g) Recommendations for improvement

## 5.6.3 Review output

The output from the management review shall include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes.
- b) Improvement of products related to customer requirements.
- c) Resource needs.

# 6. Resource Management

## 6.1 Provision of resources

CMT has determined and provides the resources needed:

- a) To implement and maintain the quality management system and continually improve its effectiveness.
- b) To enhance customer satisfaction by meeting customer requirements.

## **6.2 Human resources**

### **6.2.1 General**

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

### **6.2.2 Competence, awareness and training**

CMT:

- a) Has determined the necessary competence for personnel performing work affecting product quality.
- b) Provides training or takes other actions to satisfy these needs.
- c) Evaluates the effectiveness of the actions taken.
- d) Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- e) Maintains appropriate records of education, training, skills and experience (see par. 4.2.4).

The method in which CMT execute the above is defined in CMT documented procedure 2.7.

## **6.3 Infrastructure**

CMT has determined, provides and maintains the infrastructure needed to achieve conformity to product requirements. CMT infrastructure includes:

- a) Buildings, workspace and associated utilities,
- b) Process equipment (both hardware and software).
- c) Supporting services (such as communication).

## **6.4 Work environment**

The method in which CMT has determines and manages the work environment needed to achieve conformity to product requirements is defined in CMT documented procedure 2.10.

## 7. Product Realization

### 7.1 Planning of product realization

CMT plans and develops processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see par. 4.1).

In planning product realization, CMT has considered and related to the following:

- a) The quality objectives and requirements for the product.
- b) The need to establish processes, documents, and provide resources specific to the product.
- c) The required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
- d) The records needed to provide evidence that the realization processes and resulting product meet requirements (see par. 4.2.4).

CMT's method of realization planning is defined in CMT documented procedure 5.6.

#### Notes:

- 1) A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.
- 2) CMT also applies the customer communication requirements given in par. 7.3 to the development of product realization processes.

### 7.2 Customer-related processes

#### 7.2.1 Determination of requirements related to the product

CMT product specifications are defined by CMT product catalog. Where product requirements are changed, CMT shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. CMT reviews the contracts and verifies the determination and conformance with the following:

- a) The requirements specified by the customer.
- b) The requirements not stated by the customer but necessary for meeting the specified intended use, including the requirement for delivery and post-delivery activities.

- c) Statutory and regulatory requirements related to the product.
- d) Any additional requirements determined by CMT.

### **7.2.2 Review of requirements related to the product**

CMT reviews the requirements related to the product. This review is conducted prior to CMT's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that

- a) Product requirements are defined.
- b) Contract or order requirements differing from those previously expressed are resolved.
- c) CMT has the ability to meet the defined requirements.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by CMT before acceptance.

The method in which CMT determines and reviews the product related requirements is defined in CMT documented procedure 6.2.

Records of the results of the review and actions arising from the review are maintained (see par. 4.2.4).

### **7.2.3 Customer communication**

CMT has determined and implements effective arrangements for communicating with customers in relation to:

- a) Product information, including service and application support (see par. 7.5.1).
- b) Enquiries, contracts or order handling, including amendments (see par. 7.2.2).
- c) Customer feedback, including customer complaints (see par. 8.2.1 and 8.3).

## **7.3 Design and development**

CMT R&D documented procedures (Chapter 5) defines the methods in which CMT ensures the quality and control of design and development (as described in paragraphs 7.3.1 to 7.3.9). Throughout the design process CMT evaluate the needs for risk analysis and maintains records of any risk analysis performed.

### **7.3.1 Design and development planning**

CMT plans and controls the design and development of product. During the design and development planning, CMT determines:

- a) The design and development stages,
- b) The review, verification and validation, which are appropriate to each design and development stage.
- c) The responsibilities and authorities for design and development.

CMT manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

### **7.3.2 Design and development inputs**

Inputs relating to product requirements are determined and records maintained (see par. 4.2.4). These inputs include:

- a) Functional and performance requirements,
- b) Applicable statutory and regulatory requirements,
- c) Where applicable, information derived from previous similar designs.
- d) Other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

### **7.3.3 Design and development outputs**

The outputs of design and development are in a form that enables verification against the design and development inputs and being approved prior to release.

CMT ensures that the design and development outputs:

- a) Meet the input requirements for the design and development.
- b) Provide appropriate information for purchasing, production and for service provision.
- c) Contain or reference product acceptance criteria.
- d) Specify the characteristics of the product that are essential for its safe and proper use.

### **7.3.4 Design and development review**

At suitable stages, as defined in CMT R&D procedures (chapter 5) systematic reviews of design and development are performed in accordance with planned arrangements (see par. 7.3.1).

- a) To evaluate the ability of the results of design and development to meet requirements.
- b) To identify any problems and to propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained (see par. 7.3.9).

### **7.3.5 Design and development verification**

Verifications are performed in accordance with planned arrangements (see par. 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see par. 7.3.9).

### **7.3.6 Design and development validation**

Design and development validation are performed in accordance with planned arrangements (see par. 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Wherever practicable, as part of the design validation, CMT shall perform and maintain record of clinical evaluations. Records of the results of validation and any necessary actions are maintained (see par. 7.3.9).

### **7.3.7 Control of design and development changes**

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered (refer to CMT R&D procedure 5.5).

### **7.3.8 Design Transfer**

CMT ensures that the device design is correctly translated into production specifications according to CMT R&D procedures (chapter 5).

### **7.3.9 Design quality records**

CMT design data is recorded in the Design History File (DHF) according to CMT R&D procedure 5.10.

## **7.4 Purchasing information**

### **7.4.1 7.4.1 Purchasing process**

CMT ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

CMT evaluates and selects suppliers based on their ability to supply product in accordance with CMT's requirements.

Criteria for selection, evaluation and re-evaluation are established and records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see par. 4.2.4).

The method in which CMT ensures the above is defined in CMT documented quality procedures 2.16 and 2.17.

### **7.4.2 Purchasing information**

Purchasing information shall describe the product to be purchased, including where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment.
- b) Requirements for qualification of personnel.
- c) Quality management system requirements.

CMT shall ensure the adequacy of specified purchase requirements prior to the communication to the supplier.

The method in which CMT ensures the above is defined in CMT documented quality procedures (chapter 2), engineering procedures (chapter 8) and manufacturing procedures (chapter 9).

### **7.4.3 Verification of purchased product**

By default CMT prefer to rely on the quality of its suppliers (see par. 7.4.1) rather than on internal inspection. When necessary CMT shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements (refer to quality procedure 2.20).

Where CMT intends to perform verification at the supplier's premises, CMT shall state the intended verification arrangements and method of product release in the purchasing information.

## **7.5 Production and service provision**

### **7.5.1 Control of production and service provision**

CMT plans and carries out production and service provision under controlled conditions. The controlled conditions include:

- a) The availability of information that describes the characteristics of the product.
- b) The availability of work instructions, as necessary.
- c) The use of suitable equipment.
- d) The availability and use of monitoring and measuring devices.
- e) The implementation of monitoring and measurement.
- f) The implementation of labeling, release, delivery and post-delivery activities.

The method in which CMT ensures the above is defined in CMT documented procedures and work instructions.

The method in which CMT ensures the calibration and maintenance of measuring and monitoring equipment is defined in CMT documented quality procedure 2.23.

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

Due to the complex nature of its products CMT acceptance is based on testing of 100% of the products. Where subsequent monitoring or measurement cannot verify the resulting output of any production and/or service processes, CMT shall validate these processes. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

CMT shall establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes.
- b) Approval of equipment and qualification of personnel.
- c) Use of specific methods and procedures.
- d) Requirements for records (see par. 4.2.4).

e) Revalidation of process after change.

The method in which CMT ensures the above is defined in CMT documented quality procedure 2.9.

### **7.5.3 Identification and Trace-ability**

CMT identifies the product by suitable means throughout product realization.

CMT identifies the product status with respect to monitoring and measurement requirements.

CMT controls and records the unique identification of the product.

CMT has established and maintains the documented procedure 2.9 to ensure the above.

### **7.5.4 Customer property**

CMT processes are usually not involved with handling customer property. If and where, customer property comes under the organization control, CMT shall exercise care with the property while it is under its control or being used by CMT. CMT shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see par. 4.2.4).

The method in which CMT ensures the above is defined in CMT documented procedure 2.18.

#### Note:

Customer property can include intellectual property.

### **7.5.5 Preservation of product**

CMT preserves the conformity of the products during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation is also applied to the constituent parts of a product.

The method in which CMT ensures the above is defined in CMT documented procedure 2.27.

## 7.6 Control of monitoring and measuring devices

CMT has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see par. 7.2.1).

CMT has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment are:

- a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded.
- b) Adjusted or re-adjusted as necessary.
- c) Identified to enable the calibration status to be determined.
- d) Safeguarded from adjustments that would invalidate the measurement result.
- e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, CMT assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. CMT shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see par. 4.2.4).

The method in which CMT ensures the above is defined in CMT documented procedure 2.23.

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

## 8. Measurement, analysis and improvement

### 8.1 General

CMT plans and implements the monitoring, measurement, analysis and improvement processes needed:

- a) To demonstrate conformity of the product.

- b) To ensure conformity of the quality management system.
- c) To continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

## **8.2 Monitoring and measurement**

### **8.2.1 Customer satisfaction**

As one of the measurements of the performance of the quality management system, CMT shall monitor information relating to customer perception as to whether CMT has met customer requirements. The methods for obtaining and using this information are defined in CMT documented procedures 5.11 and 10.6.

### **8.2.2 Internal audit**

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

- a) Conforms to the planned arrangements (see par. 7.1), to the requirements of this Quality Manual and to the quality management system requirements established by CMT.
- b) Is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process.

Auditors shall not audit their own work.

The responsibilities and requirements for planned and conducting audits, and for reporting results and maintaining records (see par. 4.2.4) are defined in CMT documented quality procedure 2.29.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see par. 8.5.2).

### **8.2.3 Monitoring and measurement of processes**

CMT applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the

ability of the processes to achieve planned results. The finding shall be presented to CMT Management Reviews.

When planned results are not achieved, CMT management shall initiate corrections and corrective action, as appropriate, to ensure conformity of the product.

The method in which CMT ensures the above is defined in CMT documented procedures and work instructions.

#### **8.2.4 Monitoring and measurement of product**

CMT monitors and measures the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see par. 7.1) and the Device Master Record (DMR) requirements.

Evidence of conformity with the acceptance criteria shall be maintained in the Device History Record (DHR). Records shall indicate the person(s) authorizing release of product (see par. 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see par. 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The method in which CMT ensures the above is defined in CMT documented procedures and work instructions.

### **8.3 Control of nonconforming product**

CMT ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

CMT shall deal with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity.
- b) By authorizing its use, release or acceptance under concession by relevant authority and, where applicable, by the customer.
- c) By taking action to preclude its original intended use or application.

Records of the nature of nonconformities and subsequent actions taken, including concessions obtained, shall be maintained (see par. 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

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

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in CMT documented quality procedure 2.24.

## **8.4 Analysis of data**

CMT shall determine, collect and analyze 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. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer satisfaction (see par. 8.2.1).
- b) Conformity to product requirements (see par. 7.2.1).
- c) Characteristics and trends of processes and products including opportunities for preventive action.
- d) Suppliers.

The method in which CMT ensures the above is defined in CMT documented procedure 2.6 and 2.30.

## **8.5 Improvement**

### **8.5.1 Continual improvement**

CMT shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The methods in which CMT ensures the above is defined in this Quality Manual and the derived CMT documented procedures.

### **8.5.2 Corrective action**

CMT shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

CMT documented procedures define the requirements for:

- a) Reviewing nonconformities (including customer complaints – see note).
- b) Determining the causes of nonconformities.
- c) Evaluating the need for action to ensure that nonconformities do not recur.
- d) Determining and implementing action needed.
- e) Records of the results of action taken (see par. 4.2.4).
- f) Reviewing corrective action taken.

Note:

CMT pays special attention to handling customer complaints and their corrections in conformance with regulatory requirements applicable to medical devices (refer to CMT documented procedures 2.25 and 10.1).

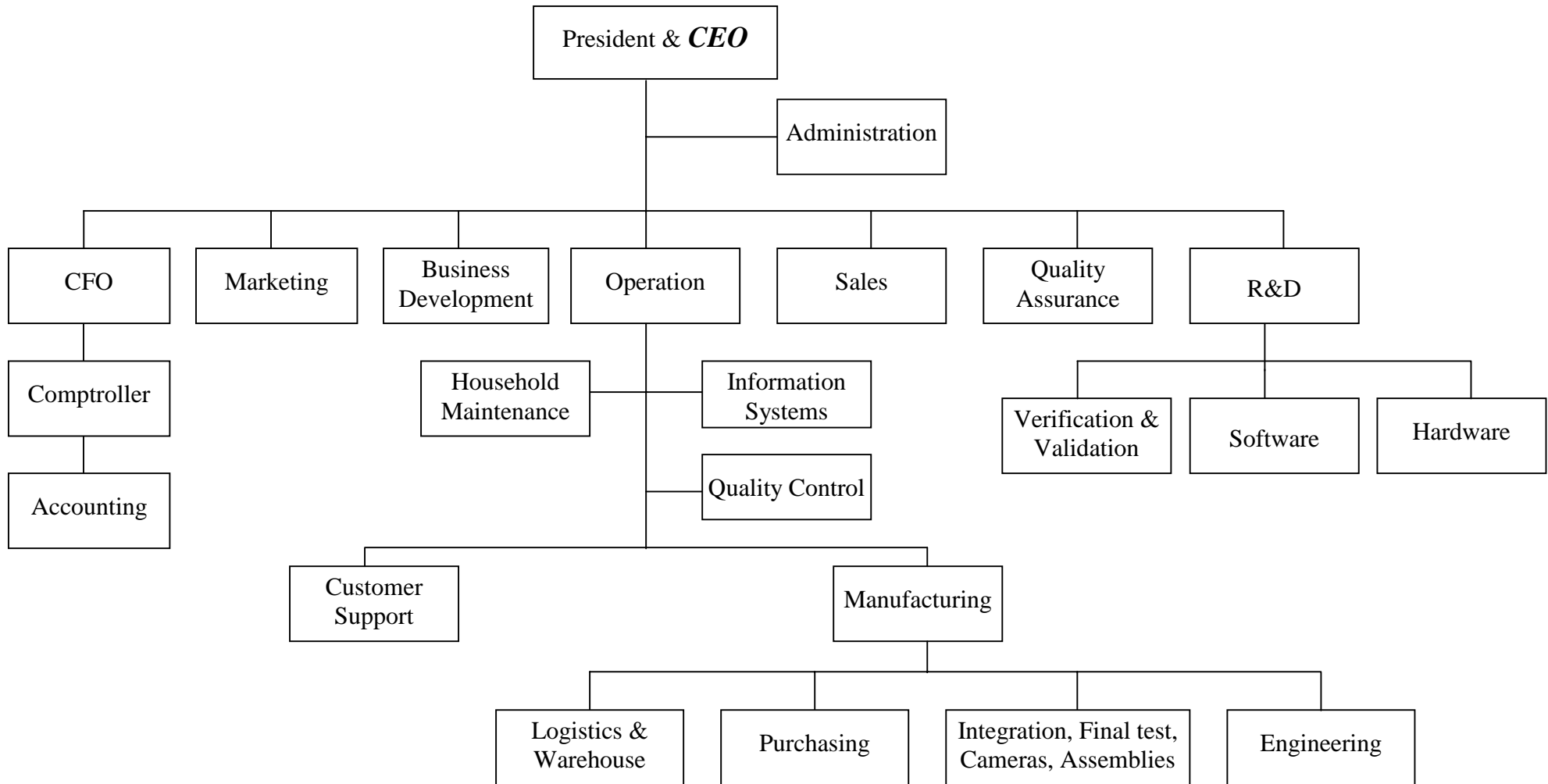
### **8.5.3 Preventive action**

CMT shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

CMT documented procedures has been established to define requirements for:

- a) Determining potential nonconformities and their causes.
- b) Evaluating the need for action to prevent occurrence of nonconformities.
- c) Determining and implementing action needed.
- d) Keeping records of results of action taken (see par. 4.2.4) and reviewing preventive action taken.

## 9. Organization Structure



## 10. CMT Areas of Responsibility & Authority

The followings summarize the topics of the organization structure and the definitions of responsibility and authority:

### 10.1 President and Chief Executive Officer (CEO)

- a. Definition of CMT business Strategy.
- b. Overall responsibility for CMT investments and budget.
- c. Overall responsibility for the company daily business process.
- d. Overall responsibility for the R&D, manufacturing, sales, QA and Marketing.
- e. Search for business opportunities that can develop and increase CMT sales.
- f. Definition and implementation of the company quality policy.
- g. Definition and implementation of the company quality targets.

### 10.2 Finance

- a. Responsible to prepare all company financial reports and all reports needed for the tax authorities, stock exchange, companies registration and any statutory body, according to the law.
- b. Responsible to check of all contract or agreement signed by CMT.
- c. Responsible for payments and communication with banks and other financial institutes.
- d. Responsible for the accounting, payments, bills, invoices and collection.
- e. Responsible for control of inventory, and the record of shipping and receiving materials and equipment.

### 10.3 Business Development Manager

- a. Responsible to the definition of future products.
- b. Responsible for markets development for the company products and the global sales agreements (OEM).
- c. Control and help to R&D, enabling development according to product definition.

## 10.4 Marketing Manager

- a. Responsible for markets development for the company products.
- b. Coordinated with the Business Development Manager, is responsible for the definition of specifications for future products and the transfer of the requirements to the R&D manager.
- c. Responsible for the marketing publications and control of CMT user manuals.
- d. Responsible for the communication with CMT customers.

## 10.5 Quality Assurance Manager

- a. Define CMT mandatory quality standards.
- b. Establish of the Company's Quality Manual and Procedures. Verify the compliance of CMT quality procedures and working instructions with predefined mandatory standards.
- c. Ensure that the Company's quality assurance and control system complies with the procedures and working instructions through audits, training, preventive and corrective actions.
- d. Evaluate the performance effectiveness by internal audits and quality record analysis.
- e. Report to CMT management about non-compliance that can impede the company from meeting its goals.
- f. Routinely present the quality status to a management review and ensure the continuing suitability and effectiveness of the quality system.
- g. Define the mandatory activities of the company, which are required by external authorities; audit their implementation and initiate, when required, corrective action.
- h. Represent the Company before regulatory authorities.
- i. Supervise and approve material presented to external regulatory authorities, such as 510(k) submissions and MDD technical files.
- j. CMT is committed to work according to external standards (ISO, EN, IEC, UL, etc.). The Quality Assurance Manager is responsible to make sure that all these reference standards, which are being used by CMT, will be available in CMT to the relevant employees. The Quality Assurance Manager is also responsible to be informed, by external sources (like the SII library), about new standards and corrections and / or updates to standards, which are related to subjects, which CMT is committed to.

- k. The Quality Assurance Manager is responsible to inform the Notified Body about:
  - 1) A new design, which is not within the scope of the CE certification.
  - 2) Substantial changes in the quality system of CMT.
- l. The Quality Assurance Manager is responsible to verify that a systematic Post Market Surveillance is conducted. CMT shall perform systematic reviews of the PMS reports in order to gain experience from the products in the post-production phase and to implement means to apply any necessary action. The results will be reported to CMT management.

## **10.6 Sales Manager**

- a. Responsible for the sales of CMT products.
- b. Implementation of contract reviews.
- c. Contact between the company and its clients in case of complaints regarding sales, deliveries and implementation of contracts.
- d. Prepare and distribute CMT product catalogs and price list.
- e. Organization of exhibitions and preparing of advertisement material.
- f. Responsible to prepare sales forecast.

## **10.7 Research and Development Manager**

- a. Develop new products.
- b. Provide technical support and backup for the manufacturing area.
- c. Serve as technical authority for CMT.
- d. Provide production files and product documentation.
- e. Provide new applications & technical solutions for CMT customers.

## **10.8 Operation Manager**

### **10.8.1 Manufacturing**

- a. Responsible for the Production Line and its logistics including assembly, integration, final tests, purchasing, storage and deliveries to customers.
- b. Responsible to prepare the production plans and to implement it according to the sales forecast.
- c. Responsible to prepare the production budget and work accordingly taking into account timetables and the quality of products.

- d. Responsible for the definitions of the production processes according to the production guidelines and production files made by the engineering department.
- e. With regard to purchasing, the Operations Manager, with the assistance of the Quality Assurance department, is responsible for the quality of purchased material.
- f. Responsible for the management of all production department manpower and the professional training of the production employees.
- g. Responsible for engineering and the company production documentation.
- h. Responsible that all work done will strictly follow CMT procedures and work instructions.
- i. Supply CMT products on time, at the required quality and cost.
- j. Support R&D in development of new products to ensure optional manufacturability and relevant tools.

### 10.8.2 Customer Support

- a. Planning and carrying out of installations of CMT products.
- b. Establish a technical support and service support program.
- c. Prepare the technical training of service personnel.
- d. Responsible to the contacts with CMT customers in any case which relates to the quality of the product, the quality of service and spare parts issues.
- e. Define and issue spare parts price list.

## 11. Approval and Validity

CMT President and CMT Quality Manager approved this Quality manual. It is valid and compulsory throughout all CMT activities.

<b>Function:</b>	President & CEO	Quality Manager
<b>Name:</b>	P. Dror	Y. Raz
<b>Signature:</b>		
<b>Date:</b>	30-May-2002	30-May-2002

## 12. Appendix A - List of applicable standards

Standard Number	Standard Name
ISO 9000:2000	Quality management systems – Fundamental and vocabulary
ISO 9001:2000	Quality management systems – Requirements
ISO 9004:2000	Quality management systems – Guidelines for performance improvements
ISO 9000-3	Quality Management and Quality Assurance Standards – Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Computer Software.
ISO 13485	Quality System – Medical Device particular requirements for the application of ISO 9001
ISO 14971:2000	Medical devices – Application of risk management to medical devices
IEC 60601-1	Medical Electronic Equipment Part 1: General Requirements for Safety
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems

## 13. Appendix B - Standards look up table

Subject	Requirement	FDA	ISO 9001		CMT Procedure
			2000	1994	
Documentation	Quality Manual		4.2.2		0102
	Quality System Procedures	820.20 e	4.2.2	4.2.1	0201 and 0202
	Control of Documents	820.40	4.2.3	4.5.2	0214
	Control of Records	820.180/6	4.2.4	4.16	0228
	Device History record (DHR)	820.184	8.2.4	4.16	0510
	Device Master File (DMR)	820.181	7.5.1	4.2.3	Engineering
	List Of Controlled External Standards		4.2.3	4.5.2	0102
Management Responsibility	Management Commitment		5.1		0102
	Regulatory Requirement		5.1	4.4.1	0102
	Customer focus		5.2		0102
	Quality Policy	820.20 a	5.3	4.1.1	0102
	Planning: Quality Objectives	820.20 d	5.4.1		0206
	Planning Of Quality M. System	820.20 d	5.4.2	4.2.3	0102
	Organization	820.20 b		4.1.2	0102
	Responsibility & Authority	820.20 b 1	5.5.1	4.1.2.1	0102
	Management Representative	820.20 b 3	5.5.2	4.1.2.3	0102
	Internal Communication		5.5.3		0102
	Management Review	820.20 c	5.6	4.1.2.4	0206
Resources Management	Provision of Resources	820.20 b 2	6.1	4.1.2.2	0102
	Human Resources: Qualification	820.25.a	6.2.2.a	4.18	0207
	Human Resources: Training	820.25 b	6.2.2.a	4.18	0207
	Human Resources: Job description, Awareness	820.25 b1,2	6.2.2.a	4.18	0207
	Human Resources: cleanliness clothing	820.70 d	6.22.a	4.18	
	Infrastructure Support		6.3	4.9	0102
	Environment, Building,	820.70 c,f	6.3	4.9	0210
	Equipment	820.70 g	6.3	4.9	0210
	Automated Process	820.70 i	6.3	4.9	0210
	Manufacturing Materials	820.70 h	6.3	4.9	0210

Subject	Requirement	FDA	ISO 9001		CMT Procedure
			2000	1994	
	Environment:	820.70 e	6.4	4.9	0210
	Environment: Safety of Employees		I	4.9	0307
	Work Environment: Preventing Internal Contamination	820.70 e	6.4 ii	4.9	0210
Product Realization	Planning of product realization		7.1		0506
	Determination of requirements related to the (sold) product		7.2.1.	4.3.1	0602
	Review of requirements related to the sold product		7.2.2	4.3.2	0602
	Customer Communication		7.2.3		0102
	Design and development Control	820.30	7.3	4.4	R&D
	Risk Management	820.30 j		4.4.1	0508
	Design and development Planning	820.30 b	7.3.1	4.4.2	R&D
	Design and development Planning: SW Design	820.30 b	7.3.1	4.4.2	R&D
	Design and development Input	820.30 c	7.3.2	4.4.4	R&D
	Design and development output	820.30 d	7.3.3	4.4.5	R&D
	Design and development Review	820.30 e	7.3.4	4.4.6	0506
	Design and development Verification	820.30 f	7.3.5	4.4.7	R&D
	Design and development Validation	820.30 g	7.3.6	4.4.8	R&D
	Design and development Validation: Clinical Experiments	820.30 g	7.3.6	4.4.8	0704
	Design Transfer	820.30 h	7.3.3 b	4.4.5	R&D
	Control of Design and development Changes	820.30 i	7.3.7	4.4.9	0505
	Purchasing Process	820.50	7.4.1	4.6	0102
	Purchasing Process, Supplier & Process Control	820.50 a	7.4.1	4.6.2	0216 and 0217
	Purchasing Information	820.50 b	7.4.2	4.6.3	0220
	Verification of purchased product	820.50 b	7.4.3	4.6.4	0220
	Production & Service Provision		7.5.1	4.9	0102e
	Production Provision - process control	820.70 a	7.5.1	4.9	0901
	Production Provision - process change control	820.70 b	7.5.1	4.9	0813
Production Provision - labeling	820.120				
Production Provision -Delivery, Distribution	820.160	7.5.1 f	4.9	0209	

Subject	Requirement	FDA	ISO 9001		CMT Procedure
			2000	1994	
Product Realization	Service Provision	820.200	7.5.1	4.19	Service
	Service Provision: Installation	820.170	7.5.1 f	4.19	Service
	Validation of Production Process	820.75	7.5.2	4.9	0210
	Validation of Service Process		7.5.2	4.19	
	Product Identification	820.60	7.5.3	4.8	0209
	Trace ability	820.65	7.5.3	4.8	0209
	Product acceptance status	820.86	7.5.3	4.12	Quality and Manufacturing
	Customer Property		7.5.4	4.7	0218
	Preservation of the Product, handling	820.140	7.5.5	4.15	0227
	Preservation of the Product, Storage	820.150	7.5.5	4.15	0227
	Control of Monitoring and Measuring devices	820.72	7.6	4.11	0223
Measurement analysis and Improvement	Customer Satisfaction		8.2.1		0511 and 1006
	Internal Audit - Quality Audit	820.22	8.2.2	4.17	0229
	Monitoring & Measurements of Process	820.70 a 2	8.2.3	4.20	Manufacturing
	Monitoring & Measurements of Product	820.80 c	8.2.4	4.10	Manufacturing
	Final Acceptance	820.80 d	8.2.4	4.10	Manufacturing
	Control of Non Conforming product	820.90	8.3	4.13	0224
	Complaint Files	820.198	8.3	4.13	0225 and 1001
	Analysis of data	820.100 a 1	8.4		0206 and 0230
	Statistical Techniques	820.50	8.4	4.20	0206 and 0230
	Continual improvement		8.5.1		0102
	Corrective action	820.100	8.5.2	4.14	Quality
	Advisory	803			
	Recall	806			
Preventive Action	820.100	8.5.3	4.14	Quality	