Shanghai Phoenix Communication & Technology Co., Ltd
No.569, Huaxu Rd., Xujing, Qingpu, Shanghai, China

INTEGRATED MANAGEMENT MANUAL

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REVISION HISTORY

Revision	Description	Revised by	Approved by	Date
A	Original Issue	Lijun Yu	Youqiang Jiang	Jun01, 2008
B	Management Representative Change	Boge Lee	Youqiang Jiang	Mar08, 2010
C	Add Requirements of ISO9001:2008	Amy Miao	Youqiang Jiang	Aug30, 2011
D	Add Requirements of ISO14001:2004	Amy Miao	Youqiang Jiang	July01, 2012
E	Add Requirements of ISO13485:2003	Amy Miao	Youqiang Jiang	June1, 2013

Manual Index

Company Introduction

Shanghai Phoenix Communication & Technology Co., Ltd. (**PCT**) was established in Nov. 2002 and is a subsidiary company of The Phoenix Company of Chicago Inc.
The company business is Design and Manufacture of Connector, Cable Assemblies, Wire Harness, Parts and Components for Transmission Applicationsin Medical Equipment &Test Instrumentation &Telecom, etc…

The products cover D-subminiature H/L Frequency Combination Connectors, RF Coaxial Connectors, Customized Connectors, LF/RF and Microwave Cable Assemblies and Wire Harness, and its component, such as Coaxial Cables, Connectors, etc…

This manual specify PCT manufactured products follow the American Military Standard， customer standard or customized, Phoenix or PCT products standard, and quality & environment system requirements imposed by the applicable regulatory authorities

This manual is available to customer, supplier and any 3rd party, and can be obtained through company's Website or our sales.

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1.0 Scope

Shanghai Phoenix Communication & Technology Co.,Ltd, located inNo.569, Huaxu Road, Xujing Town, Qingpu, Shanghai, P.R.China, hereafter referred to as “PCT”, shall implement an integrated management system which includes a quality management system and an environmental management system, that demonstrates the capability to consistently provide conforming product meeting regulations requirements and customer’s requirements. And it also demonstrates PCT’s environmental management.

This management system is applicable to:

a. ISO9001:2008: Design and Manufacture of Connector, Cable Assemblies, Wire Harness, Parts and Components for Transmission Applications

b. ISO14001:2004:Environmental management activities related to Design and Manufacture of Connector, Cable Assemblies, Wire Harness, Parts andComponents for Transmission Applications

c. ISO13485:2003:Manufacture of Connector, Cable Assemblies, Wire Harness, Parts and Components In Medical Equipment

1.1 Reduction in Scope

The manual is applied to all items in ISO9001:2008.
PCT is providing appendix for Medical Equipment, and design is provided by customer, therefore, ISO13485:2003 section 7.3 Design and Development is excluded from the management system. Meanwhile, PCT products don’t belong to sterile medical devices and implanted medical devices, so the following sections (including all related sections) of the ISO13485:2003 standard are considered as non-applicable to PCT:

- Section 7.5.1.2.2 “Installation activities” and section 7.5.1.2.3 “Servicing activities”
- Section 7.5.1.3. “Control of production and service provision: Particular requirements for sterile medical devices”
- Section 7.5.2.2. “Validation of processes for production and service provision: Particular requirements for sterile medical devices”
- Section 7.5.3.2.2. “Traceability: Particular requirements for active implantable medical devices and implantable medical devices”
- Section 8.2.4.2. “Particular requirements for active implantable medical devices and implantable medical devices”

2.0 Normative References

PCT’s integrated management system will comply with the most recent standards
ISO9001:2008, *Quality management systems – Requirements*
ISO13485:2003, *Medical Devices – Quality management systems – Requirements for regulatory purposes*
ISO14001:2004, *Environmental management systems - Requirements with guidance for use*

Where other national standards or regulations require adherence, they too shall be applied.

3.0 Terms and Definitions

For the purpose of this manual, the terms and definitions given in ISO9000:2005*Quality management systems – Fundamentals and vocabulary*, and ISO13485:2003*Medical device-Quality management*

system-requirements for regulatory, and ISO14001:2004*Environmental management systems -Requirements with guidance for use*apply.

Throughout this Manual, the term “procedure” means a documented procedure that is established, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by one or more documents.

4.0 Integrated Management System Requirements

4.1 General Requirements

PCT shall establish, document, implement, and maintain an integrated management system and maintain its effectiveness in accordance with the requirements of Section 2.0, Normative References. To implement and document the system, PCT shall:

a. Identify the processes needed for the integrated management system and their application throughout the organization
b. Determine the sequence and interaction of these process
c. Determine the criteria and methods required to ensure that both the operation and control of these processes is effective
d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
e. Measure, monitor, analyze processes
f. Implement actions necessary to achieve planned results and continually improve the effectiveness of these processes

Where PCT chooses to outsource any process that affects product conformity with requirements (partial molding parts, transportation and so on), PCT will follow purchasing procedure to control these processes and ensure to conformity to all customers, statutory and legal requirements.

4.2 Documentation Requirements

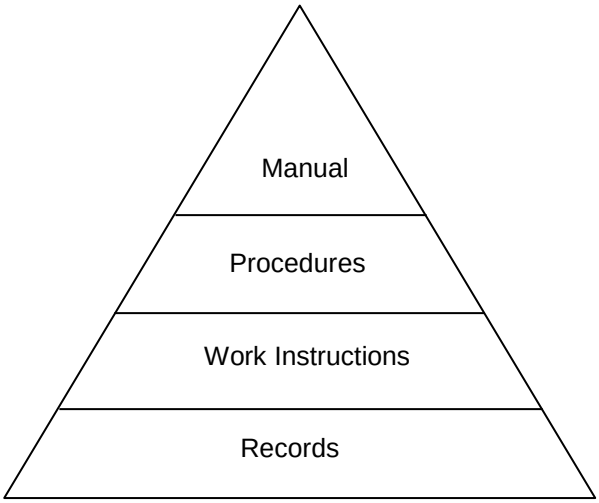
4.2.1 General

PCT management system documentation shall include, at a minimum:

a. Documented statements of a management policy and objectives
b. This integrated management manual
c. Procedures necessary to implement requirements of Section 2.0 Normative References
d. Documents needed to ensure the effective planning, operation and control of processes
e. Records necessary to implement requirements of Section 2.0 Normative References
f. Any other documentation specified by national or regional regulations

PCT shall establish and maintain a file for each type or model of parts used in medical equipment, which contains or identifies documents defining product specifications and quality system requirements. These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

The Documentation can be in any form or type of medium.
PCT documents structure:



Note: All Procedures and Work Instructions may touch upon PCT's productandprocess information,therefore, all above information may be confidential to customer, supplier and any 3rd party.

4.2.2 Integrated Management Manual

This Integrated Management Manual is established and maintained and includes:

a. The scope of the integrated management system, including details of and justification for any exclusion and/or non-application
b. Reference to the procedures established to implement the integrated management system (including a procedure which describes the structure of the documentation)
c. A description of the interaction between elements of the integrated management system

4.2.3 Control of Documents

PCT shall establish and maintain procedures to control documents. The procedures shall ensure that:

a. Documents are reviewed and approved for adequacy prior to issue
b. Documents are reviewed and updated as necessary and re-approved
c. Changes and the current revision status of documents are identified
d. The current versions of relevant documents are available at points of use
e. Documents are legible, readily identifiable, and retrievable
f. Documents of external origin determined to be necessary for the planning and operation of the management system are identified and their distribution controlled
g. Obsolete documents are removed from all points of issue and use, or otherwise controlled to prevent unintended use
h. Obsolete documents retained for any purpose are suitably identified

For parts used in medical equipment, changes to documents should be reviewed and approved either by the original approving function or by another designated function that has access to pertinent background information upon which to base its decisions.

PCT shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which parts used in medical equipment have been manufactured and tested are available for at least the lifetime of the parts as defined by PCT,

but not less than the retention period of any resulting record or as specified by relevant regulatory requirements.

4.2.4 Control of Records

PCT shall ensure that:

a. Records are established and maintained to provide evidence of conformance to specified requirements and of the effective operation of the integrated management system.
b. Records remain legible, readily identifiable, and retrievable
c. A procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records

For parts used in medical equipment, PCT shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by PCT, but not less than two years from the date of product release by PCT or as specified by relevant regulatory requirements.

5.0 Management Responsibility

5.1 Management Commitment

Top management shall provide evidence of its commitment to the development and implementation of the integrated management system and maintain its effectiveness by:

a. Communicating to PCT the importance of meeting customer as well as statutory and regulatory requirements related to the safety of product and its environmental aspects
b. Establishing the management policy
c. Ensuring that quality objectives are established
d. Conducting management reviews, and
e. Ensuring the availability of resources

5.2Customer and Environment Focus

Top management shall ensure customer requirements and requirements related to PCT's environmental aspectsare determined and met.

5.3Management Policy

Top management shall ensure that the management policy

a. is appropriate to the purpose of PCT and to the nature, scale and environmental impacts of its activities, products and services
b. includes a commitment to comply with requirements and to maintain the effectiveness and to continual improvement and prevention of pollution
c. provide a framework for establishing and reviewing objectives
d. is communicated and understood within PCT, and
e. is reviewed for continuing suitability
f. is available to the public

The management policy of PCT is defined below:

COMPLY WITH LAWS AND REGULATIONS
FOCUS ON CUSTOMER SATISFACTION
PREVENT ENVIRIONMENTALPOLLUTION
COMMIT TO CONTINOUS IMPROVEMENT

5.4Planning

5.4.1Environmental Aspects

PCT shall establish, implement and maintain a procedure (s)

a. To identify the environmental aspects of its activities and products within the defined scope of the management system that it can control and those it can influence taking into account planned or new developments, or new or modified activities, products and services, and
b. To determine those aspects that have or can have significant impact (s) on the environment

PCT shall document this information and keep it up to date.

5.4.2Legal and other requirements

PCT shall establish, implement and maintain a procedure (s)

a. To identify and have access to the applicable legal requirements and other requirements related to PCT's environmental aspects, and
b. To determine how these requirements apply to its environmental aspects

5.4.3Objectives and Targets

Top management shall ensure that company objectives are establishedat relevantfunctions and levels within PCT. The objectives shall be measurable, where applicableandconsistent with the management policy and the commitment to continuallyimprovement.

PCT defines below items as company objectives, but not limited to:

a. Customer OTD (on-time delivery) rate
b. Customer returns PPM (parts per million)
c. PCT internal nonconformance – FQA PPM
d. Lead time improvement for quotation and sample (RFQ and RFS)
e. Productivity
f. Cost reduction
g. Laws and regulations compliance rate
h. First Article approval rate by first submission

5.4.4Programme(s)

PCT shall establish, implement and maintain a programme for achieving environmental objectives. Programmeshall include designation of responsibility, the means and time-frame by which the objectives are to be achieved

5.4.5Integrated Management System Planning

a. Top management shall ensure that planning is carried out in order to meet the objectives, the management system requirements and continual improvement of management system
b. Planning shall ensure that change is conducted in a manner that the integrity of the management system is maintained

5.5Responsibility, authority and communication

5.5.1 Responsibility and Authority

In general, the organization chart defines the relationship of the various functions within PCT, which should indicate the title, interaction of personnel with listing a revision number and issue date.

In particular, responsibilities and authorities appear on the documented procedures and job descriptions. PCT shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

In addition, each member of management is ultimately responsible for:

a. Implementing and communicating the management policy and requirements of integrated management system throughout their respective departments
b. Assuring that requirements of the integrated management system are available and followed by each employee
c. Ensuring that employees are proved with proper training to perform the duties required of their position
d. Initiating actions to prevent the occurrence of any nonconformance

5.5.2 Management Representative

Quality Manager is given the responsibility of Management Representative, who has the authority and responsibility to:

a. Assist General Manager in charge of the integrated management system of PCT, ensuring that processes needed are established, implemented and maintained, and report to General Manager directly.
b. Report to the General Manager on the performance of the integrated management system and area to improvement
c. Ensure the promotion of awareness of regulatory, customer satisfaction and requirements throughout the organization
d. Communicate with external parties relating to the integrated management system.

5.5.3 Communication

PCT shall establish and maintain procedures for internal communication between the various levels andfunctions regarding the effectiveness of the system and environmental aspects.Communication methods include but not limited:

a. Posting information on bulletin boards
b. Holding meetings or
c. Circulating information via e-mail or copies of documents.

Besides above, procedures shall also include receiving, documenting and responding to relevant communication from extent interested parties.

5.6 Management Review

On an annual basis PCT management shall review and evaluate the suitability, adequacy, and effectiveness of the integrated management system, including the need for changes.

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 product conformance and environmental performance, status of preventive and corrective actions, market strategies, information on new or revised regulatory requirements, follow-up actions from previous management reviews, changes that could affect the management system, and recommendations for improvement，new or revised regulatory requirement.

The output of management review shall include actions related to improvements of the integrated management system and its process, improvements of product related to customer requirements, and resources needed to achieve improvement.

The input and output of management review will be documented.

6.0 Resource Management

6.1 Provision of Resources

PCT shall determine and provide in a timely manner, the resources needed to establish, implement, maintain and improve the integrated management system and meet customer and regulatory requirements.

6.2 Human Resources

6.2.1 Assignment of personnel

PCT shall determine the requirements of each position and assign personnel who are competent to perform the responsibilities of the integrated management system based upon applicable education, training, skills and experience.

6.2.2 Training, Awareness, and Competency

PCT shall establish and maintain a 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, skill, and experience
e. Ensure that employee are aware of the relevance and importance of their activities and how contribute to the achievement of objectives and meeting customer and regulatory requirements.

6.3 Infrastructure

PCT shall determine, provide, and maintain the infrastructure needed to achieve conformity to customer and regulatory requirements. Infrastructure includes:

a. Workspace and suitable building design to perform operations, prevent mix-ups and product damage
b. Processing and measurement equipment, hardware, and software
c. Suitable maintenance and ongoing preventive maintenance of equipment and building
d. PCT shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained.

6.4 Work Environment

PCT shall define and implement those human and physical factors needed to provide services that confirm to customer and regulatory requirements, such as temperature, humidity, ventilation, lighting, drumming noisingand safety and health, etc…

The following requirements shall apply for parts used in medical equipment:

a. Establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product
b. If work environment conditions can have an adverse effect on product quality, PCT shall establish documented requirements for the work environment conditions can documented procedures or work instructions for monitor and control these work environment conditions.
c. Ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.
d. If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the environment or personnel.

7.0 Product Realization

7.1 Planning of Product Realization

PCT shall plan and develop the processes needed for product realization. Planning of processes shall be consistent with the other requirements of the integrated management system and shall be documented in a manner suitable for the operation. In planning the processes for realization of product, the following shall be determined, as appropriate:

a. Requirements for the product, test or training
b. The processes, documents, and resources to meet requirements
c. The required verification, validation, monitoring, inspection, and test activities, and criteria for product acceptance
d. Maintain records as the results of process control measures, to provide evidence of conformance
e. PCT shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained

7.2 Customer-Related Processes

7.2.1 Identification of Customer Requirements

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

a. Product requirements, including the requirements for delivery

b. Requirements not specified by the customer but necessary for fitness of purpose
c. Regulatory and legal requirements
d. Any additional requirements determined by PCT

7.2.2 Review of requirements related to the product

PCT shall review the requirements related to the product prior to commitment to supply a product, and shall ensure that:

a. The requirements are clearly defined and documented
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. PCT has the ability to meet the defined requirements

7.2.3 Customer Communication

PCT identifies sales department as the designated function for effective communication with customers in relation to product information, enquiries, contracts or order handling including amendments and customer feedback, customer complaints and advisory notices.

7.3 Design and Development

7.3.1 Design and development planning

During the design and development planning, PCT shall determines:

a. The design and development stages
b. The review, verification and validation, and design transfer activities that are appropriate at each design and development stages, and
c. The responsibilities and authorities for design and development

7.3.2 Design and Development Inputs

Inputs relating to product requirements shall be determined and records maintained. These inputs shall include:

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

7.3.3 Design and Development Outputs

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

a. Show that the input requirements for the design and development have been met
b. Provide appropriate information for successful execution of the designed process including process specifications and tolerances
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, systematic reviews involving appropriate individual(s) representing the various functions involved in the design and development shall be conducted

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

Results and necessary actions shall be documented and maintained.

7.3.5 Design and Development Verification

Verification shall be performed through review of FA 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 or at the facility prior to implementation of production. 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 and products delivered.

7.4 Purchasing

7.4.1 Purchasing Process

Methods, procedures and requirements shall be defined and implemented for suppliers and service providers to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be independent upon the effect of the purchased product on subsequent product realization or the final product.Documented procedures for evaluation and re-evaluation, and selectioncriteria shall be established.

Related records shall be maintained.

7.4.2 Purchasing Information

Methods, procedures and requirements shall be developed for the purchase of suppliers and clearly communicated, defined, and understood by the vendors through the use of contracts, specifications, drawings or purchasing orders

Purchasing documents shall include appropriate information to provide adequate qualification and

approvalof purchased products. Where appropriate, requirements for approval or qualification of product, procedures, processes, equipment, personnel and management system will be defined

Purchasing documents are reviewed for accuracy and completeness prior to release by authorized Individuals. Relevant purchasing information shall be maintained.

For parts used in medical equipment, to the extent requirement for traceability given in 7.5.3, PCT shall maintain relevant purchasing information, such as documents and records.

7.4.3 Verification of Purchased Product

PCT shall define and establish methods for the verification of purchased parts for conformance to thespecified requirements. The records shall be maintained.

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

7.5 Production and Services Provision

7.5.1 Control of Production

PCT shall plan and carry out productions provision under controlled conditions. As applicable, this shall include:

a. the availability of information that describes the characteristics of the product
b. the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary
c. the use of suitable equipment
d. the suitable work environment
e. the implementation of monitoring and measurement
f. the availabilities and use of monitoring and measuring devices
g. the implementation of defined operations for labeling and packaging
h. the implementation of release, delivery and post-delivery activities
i. establishing and maintaining a record for each batch of medical devices that provides traceability to the extent specified and identifies the amount manufactured and amount approved for distribute. The batch record shall be verified and approved.

7.5.1.1 Cleanliness of product and contamination control

PCT shall establish documented requirements for cleanliness of product if

a. product is cleaned prior to its use
b. product is supplied non-sterile to be subjected to a cleaning process prior to its use
c. product is supplied to be used non-sterile and its cleanliness is of significance in use
d. process agents are to be removed from product during manufacture

7.5.1.2 Installation activities

For parts used in medical equipment, installation requirements depend on product structure and shape and they are defined in customer's drawing.

7.5.1.3 Servicing activities

If servicing is a specified requirement, PCT shall establish documented procedures, work instructions and reference materials and reference measurement procedures. Records of servicing activities carried out shall be maintained.

7.5.2 Validation of Processes

PCT shall validate any processes for production and service provision where the resulting output can't be verified by subsequent monitoring or measurement.

PCT shall establish the documented procedure for validation, including software validation, to define and address:

a. The process to be qualified prior to use
b. The use of qualified equipment and/or personnel
c. The specific procedures and necessary documents
d. Re-validation requirements
e. Requirements for records

PCT shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software application shall be validated prior to initial use. Records of validation shall be maintained.

7.5.3 Identification and Traceability

Documented procedures shall be established for identification, traceability and status of product. Such procedures shall define the extent of product traceability and the records required. The identification of product status shall be maintained throughout product realization.

PCT shall ensure parts used in medical equipment returned are identified and distinguished from conforming product, and shall identify the product status with respect to monitoring and measurement requirements.

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

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.

Customer property can include intellectual property or confidential health information.

7.5.5 Preservation of Product

PCT shall establish work instruction for preserving the conformity of product during internal

Processingand delivery to the intended destination. This preservation shall include identification, handling,packaging, storage, and protection.

PCT shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage condition shall be controlled and recorded.

7.6 Control of Monitoring and Measuring Devices

PCT shall establish documentedprocedures to control, calibrate, and maintain measurement and monitoring equipment(device) used to demonstrate the conformance of the processes to specified requirements.The procedures shall 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. PCT 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 such standard exist, the basis used for calibration must be documented.
c. Establish, document, and maintain calibration procedures, including details of equipment type, identification no., 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 approval 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 handing, 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.

7.7 Operational control

PCT shall identify and plan those operations that are associated with the identified significant environmental aspects consistent with its environmental policy, objectives and targets, in order to ensure that they are carried out under specified conditions, by establishing, implementing and maintaining a documented procedureto control situations where their absence could lead to deviation from the policy, objectives and targets, and procedures related to the identified significant environmental aspects of goods and services and communicating applicable procedures and requirements to suppliers, including contractors.

7.8 EmergencyPreparedness and Response

Procedures for emergency shall be made and maintained to identify potential accident and emergency

situations, and stipulate each departmentmake right immediate responseaccording to emergency response plan and program, and prevent or reduce thecorresponding environment impact, disease and injury.

8.0 Measurement, Analysis, and Improvement

8.1 General

PCT 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 management system
c. Continually maintain and improve the effectiveness of the management system.

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

8.2 Measurement and Monitoring

8.2.1Customer Satisfaction/Feedback

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

For parts used in medical equipment, a documented procedure should be established to provide early warning of quality problems and for input into the corrective and preventive action processes.
If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system.

8.2.2 Internal Audit

PCT shall perform internal audit to assure effective implementation and compliance to the integrated management system, regulations, and international standards, and the methods used to measure and monitor the 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 audit.

PCT shall have a procedure for internal audits that includes:
a. Audit scope, methodology and frequency
b. Responsibilities and requirements for conducting audits
c. Timely corrective action on findings during the audit and reporting results to management
d. Follow-up actions to verify the implementation of corrective action, and reporting the verification result

8.2.3 Measurement and Monitoring of Process

PCT 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.

8.2.4 Monitoring and Measurement of Product

PCT shall establish procedures for receiving, in process, and final inspection activities as they relate to processes to confirm to specified acceptance criteria. Evidence of conformity to acceptancecriteria shall be documented and records shall indicate the authority responsible for the release ofproducts.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless they have approval from authorized person or from customer where applicable. For parts used in medical equipment, product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

8.2.5 Monitoring and Measurement of Environmental Impact

PCT shall establish, implement and maintain a procedure(s) to monitor and measure, on a regular basis, the key characteristics of the operations that can have a significant environmental impact.

Consistent with PCT's commitment to compliance, PCT shall establish, implement and maintain a procedure for periodically evaluating compliance with applicable legal requirement.

8.3 Control of Nonconforming Product and Nonconformity

8.3.1 Control of Nonconforming Product

PCT 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 to provide the identification, documentation, evaluation, segregation and disposition of nonconforming product.

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

PCT shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained.

Records of the nature of nonconformities and any subsequent action taken, including concessions obtained, shall be maintained.

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

8.3.2 Control of Nonconformity

PCT shall establish, implement and maintain a procedure for dealing with actual and potential nonconformityand for taking corrective action and preventive action. The procedure shall define requirements for :

a. Identifying and correcting nonconformity and take actions to mitigate their environmental impacts
b. Investigate and determine the causes and implementing actions to avoid recurrence.

Action taken shall be appropriate to the magnitude of the problem and the environmental impacts encountered.

8.4 Analysis of Data

PCT shall establish documented procedures to determine, collect and analyze appropriate data to determine the suitability and effectiveness of the management system and to evaluate where improvement of the effectiveness of the system can be made.
The analysis of data shall provide information relating to:
a. customer feedback
b. conformity to product requirements
c. characteristics and trends of processes and products including opportunities for preventive action, and
d. suppliers.

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

8.5 Improvement

8.5.1 General

PCT shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the management system through the use of the policy, objective, audit results, analysis of data, corrective and preventive actions and management review.

PCT shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

Records of all customer compliant investigations shall be maintained. If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved.

If any customer compliant is not followed by corrective and/or preventive action, the reason shall be Authorized and recorded.

If national or regional regulations require notification of adverse events that meet specified reporting Criteria, PCT shall establish documented procedures to such notification to regulatory authorities.

8.5.2 Corrective Action

PCT 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.
A documented procedure shall be established to define requirements for:

a. reviewing nonconformities (including customer complaints)

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, if appropriate, updating documentation
e. records of the results of any investigation and of the action take, and
f. reviewing corrective action taken and its effectiveness.

8.5.3 Preventive Action

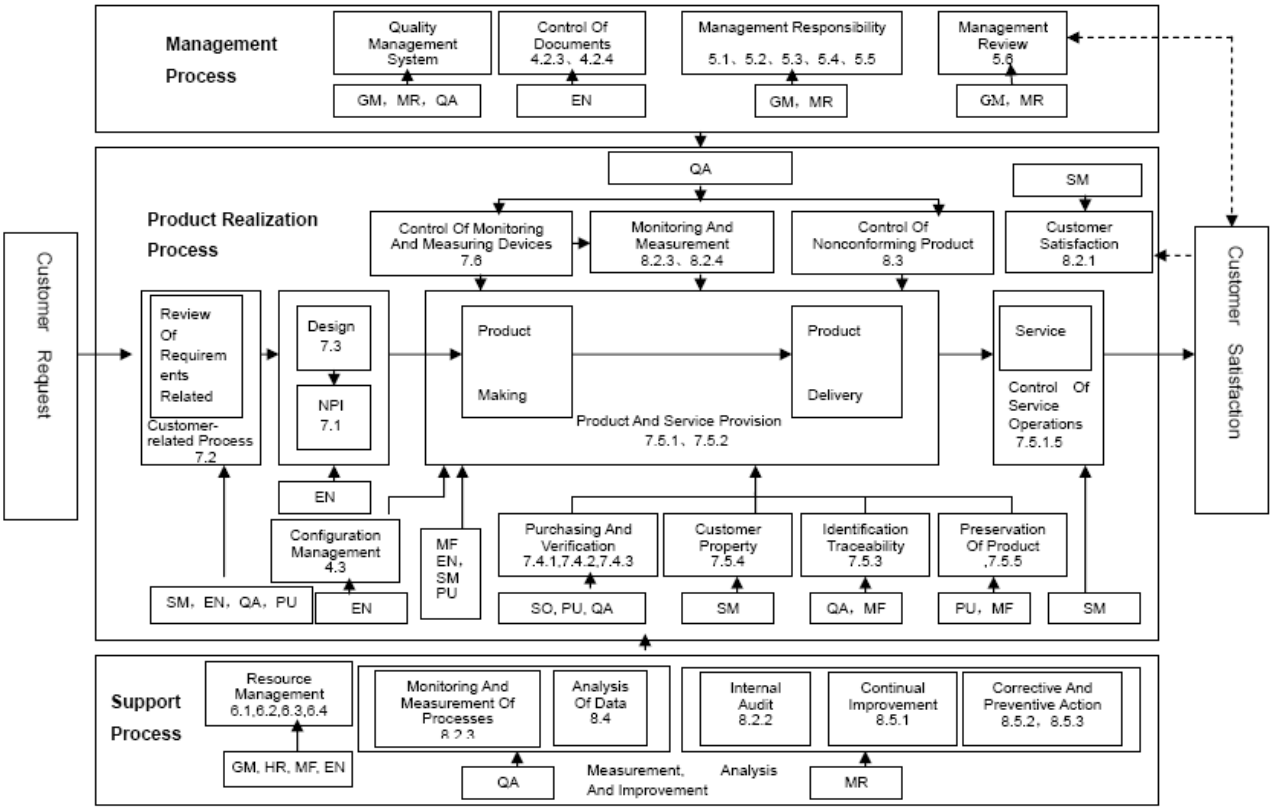
PCT shall take action to eliminate the cause of potentialnonconformities in order to prevent occurrence.
Preventive actions shall be appropriate to the effects of the potential problems.
A documented procedure shall be established to define requirements for:
a. determining potential nonconformities and causes
b. evaluating the need for action to prevent occurrence of nonconformities
c. determining and implementing action needed,
d. records of the results of any investigation and of the action take, and
e. reviewingpreventive action taken and its effectiveness.

Appendix A
References to Integrated Management System Procedures

The manual items	ISO9001 items	ISO14000 items	ISO13485 items	PCT Procedures
4.0	4	4	4	
4.1	4.1	4.1	4.1	<Integrated Management Manual> (QEM001)
4.2 4.2.1 4.2.2 4.2.3 4.2.4	4.2 4.2.1 4.2.2 4.2.3 4.2.4	4.4.4 4.4.5 4.5.4	4.2 4.2.1 4.2.2 4.2.3 4.2.4	<Integrated Management Manual> (QEM001) <Control of Document>(PD_QA_110) <Control of Record>(PD_QA_111)
5.0	5		5	
5.1	5.1	4.2	5.1	<Integrated Management Manual> (QEM001)
5.2	5.2	4.3.1	5.2	<Integrated Management Manual> (QEM001)
5.3	5.3	4.2	5.3	<Integrated Management Manual> (QEM001)
5.4 5.4.1 5.4.2 5.4.3 5.4.4 5.4.5	5.4 5.4.1 5.4.2	4.3 4.3.1 4.3.2 4.3.3	5.4 5.4.1 5.4.2	<Integrated Management Manual> (QEM001) PD_EM_001 PD_EM_002 PD_EM_003 PD_EM_004 PD_EM_005
5.5 5.5.1 5.5.2 5.5.3	5.5 5.5.1 5.5.2 5.5.3	4.4.1 4.4.3	5.5 5.5.1 5.5.2 5.5.3	<Integrated Management Manual> (QEM001) Job Descriptions
5.6	5.6	4.6	5.6	<Management Review> (PD_GM_100)
6.0	6		6	
6.1	6.1	4.4.1	6.1	<Recruitment> (PD_HR_102)
6.2	6.2	4.4.2	6.2	<Training> (PD_HR_102)
6.3	6.3	4.4.1	6.3	<Equipment Management> (PD_MF_107)
6.4	6.4	4.4.1	6.4	<Production Environment Control> (PD_MF_108)
7.0	7		7	
7.1	7.1		7.1	<Risk Control Procedure> (PD_EN_117)
7.2	7.2		7.2	<Customer Related Process> (PD_SM_103) <Delivery and Service Control> (PD_SM_124) <Control of Advisory Notice> (PD_QA_118)
7.3	7.3		7.3	<Design and Development> (PD_EN_106)
7.4	7.4		7.4	<Management of Supplier> (PD_SO_104) <Purchasing Management>(PD_PU_105)
7.5 7.5.1 7.5.2 7.5.3 7.5.4 7.5.5	7.5 7.5.1 7.5.2 7.5.3 7.5.4 7.5.5		7.5 7.5.1.1 7.5.1.2 7.5.1.2.1 7.5.1.2.2 7.5.1.3	<Process Control> (PD_MF_109) <Identification and Traceability Control> (PD_QA_119) <Software and Process Conformation> (PD_QA_125) <Customer Property Control> (PD_SM_120) <Product Protection Control> (PD_MF_121)

			7.5.2 7.5.3.1 7.5.3.2 7.5.3.2.1 7.5.3.2.2 7.5.3.3	<Delivery and Service Provision> (PD_SM_124)
7.6	7.6	4.5.1	7.6	<Control of Monitoring and Measurement Devices> (PD_QA_115)
7.7		4.4.6		PD_EM_006 PD_EM_007 PD_EM_008 PD_EM_009 PD_EM_010 PD_EM_011
7.8		4.4.7		<Emergency Preparedness and Response> (PD_EM_013)
8.0	8		8	
8.1	8.1		8.1	
8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5	8.2 8.2.1 8.2.2 8.2.3 8.2.4	4.5.4 4.5.1 4.5.5 4..5.1 4.5.2	8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.4.1 8.2.4.2	<Monitoring and Measurement of Product> (PD_QA_116) <Feedback and Accident Control> (PD_QA_123)
8.3 8.3.1 8.3.2	8.3	4.5.2	8.3	<Control of Nonconforming Products> (PD_QA_113)
8.4	8.4		8.4	<Data Analysis> (PD_QA_122)
8.5	8.5	4.2 4.5.3	8.5 8.5.1	<Corrective and Preventive Actions> (PD_QA_114)

Appendix B
References to System Processes and Interactions



Appendix C
References to PCT Processes and Responsibility

Items in the manual			Responsibilities Note: ◆--- Key △--- Minor							
			General Manager	Management Representative	HR	Sales	QA	Purchasing	Engineering	Production
4.1	General Requirements		◆	△	△	△	△	△	△	△
4.2	Documents Requirements			◆	△	△	△	△	△	△
	4.2.1	General		◆	△	△	△	△	△	△
	4.2.2	Integrated Management Manual	◆	△	△	△	△	△	△	△
	4.2.3	Control of Document		△	△	△	△	△	◆	△
	4.2.4	Control of Records		△	△	△	△	△	◆	△
5.1	Management Commitment		◆	△	△	△	△	△	△	△
5.2	Customer and Environment Focus		◆	△	△	△	△	△	△	△
5.3	Management Policy		◆	△	△	△	△	△	△	△
5.4	Planning		◆	△	△	△	△	△	△	△
	5.4.1	Environmental Aspects	△	△	△	△	◆	△	△	△
	5.4.2	Legal and Other Requirements	△	△	△	△	◆	△	△	△
	5.4.3	Objectives and Targets	◆	△	△	△	△	△	△	△
	5.4.4	Programme(s)	◆	△	△	△	△	△	△	△
	5.4.5	Integrated Management System Planning	△	◆	△	△	△	△	△	△
5.5	Responsibility, Authority, and Communication		◆	△	△	△	△	△	△	△
	5.5.1	Responsibility and Authority	◆	△	△	△	△	△	△	△
	5.5.2	Management Representative	△	◆	△	△	△	△	△	△
	5.5.3	Communication	△	◆	△	△	△	△	△	△
5.6	Management Review		◆	△	△	△	△	△	△	△
6.1	Provision of Resources		◆							
6.2	Human Resources		△	△	◆	△	△	△	△	△
6.3	Infrastructure		△	△	△	△	△	△	△	◆
6.4	Work Environment		△	△	△	△	△	△	△	◆
7.1	Planning of Product Realization		△	△	△	△	△	△	◆	△
7.2	Customer-Related Process		△	△		◆	△	△	△	△
7.3	Design and Development			△		△	△	△	◆	△
7.4	Purchasing			△			△	◆	△	△
7.5	Production and Service Provision			△		△	△	△	△	◆
	7.5.1	Control of Production		△		△	△	△	△	◆
	7.5.2	Validation of Processes		△		△	△	△	◆	△
	7.5.3	Identification and Traceability				△	△	△	△	◆
	7.5.4	Customer Property				△	△	△	◆	△
	7.5.5	Preservation of Product				△	△	◆	△	◆
7.6	Control of Measurement & Monitoring Devices						◆		△	△
7.7	Emergency Preparedness and Response				◆	△	△	△	△	△
8.1	General			◆	△	△	△	△	△	△
8.2	Measurement and Monitoring			◆			△	△	△	△

	8.2.1	Customer Satisfaction/Feedback				◆	△			
	8.2.2	Internal Audit	△	◆	△	△	△	△	△	△
	8.2.3	Monitoring and Measurement of Process	△	◆	△		△	△	△	△
	8.2.4	Monitoring and Measurement of Product					◆		△	△
	8.2.5	Monitoring and Measurement of Environmental Impact			△	△	◆	△	△	△
8.3	Control of Nonconforming Product and Nonconformity					△	◆	△	△	△
	8.3.1	Control of Nonconforming Product				△	◆	△	△	◆
	8.3.2	Control of Nonconformity			△	△	◆	△	△	△
8.4	Analysis Data		△	△	△	△	◆	△	△	△
8.5	Improvement		◆	△	△	△	△	△	△	△
	8.5.1	General	◆	△	△	△	◆	△	△	△
	8.5.2	Corrective Action	△	△	△	△	◆	△	△	△
	8.5.3	Preventive Action	△	△	△	△	◆	△	△	△

Appendix D
References to PCT Organization Chart