QUALITY MANAGEMENT SYSTEM

QMS-001

Roles	Name	Date	Signature
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(A) Table of Contents

Chapter No.	Subject	Page No.	ISO 13485 References
	Section–1		
1.	Cover page, table of contents and authorization statement	1 – 5	==========
2.	Company profile, scope	6 – 8	==========
3.	Control and distribution	9 – 10	==========
	Section–2		
4.	**Quality Management System**	10 – 14	4.0
	General requirements		4.1
	Documentation requirements		4.2
	General		4.2.1
	Quality manual		4.2.2
	Medical device file		4.2.3
	Control of documents		4.2.4
	Control of records		4.2.5
5.	**Management Responsibility**	14 – 17	5.0
	Management commitment		5.1
	Customer focus		5.2
	Quality Policy		5.3
	Planning		5.4
	Quality objectives		5.4.1
	Quality management System planning		5.4.2
	Responsibility, authority and communication		5.5
	Responsibility and authority		5.5.1
	Management representative		5.5.2

	Internal communication		5.5.3
	Management review		5.6
	General		5.6.1
	Review input		5.6.2
	Review output		5.6.3
6.	**Resource Management**	17 – 19	6.0
	Provision of resources		6.1
	Human resources		6.2
	Infrastructure		6.3
	Work environment and contamination control		6.4
	Work environment		6.4.1
	Contamination control		6.4.2
7.	**Product Realization**	19 – 25	7.0
	Planning of product realization		7.1
	Customer Related Processes		7.2
	Determination of requirements related to product		7.2.1
	Review of requirements related to product		7.2.2
	Communication		7.2.3
	Design and development		7.3
	Purchasing		7.4
	Purchasing process		7.4.1
	Purchasing information		7.4.2
	Verification of purchased product.		7.4.3
	Refurbishing and service provision		7.5
	Control of Refurbishing and service provision		7.5.1
	Cleanliness of product		7.5.2
	Installation activities		7.5.3
	Servicing activities		7.5.4
	Particular requirements for sterile medical devices		7.5.5
	Validation of processes for Refurbishing and service provision		7.5.6
	Particular requirements for validation of processes for sterilization and sterile barrier Systems		7.5.7
	Identification		7.5.8
	Traceability		7.5.9
	Customer property		7.5.10
	Preservation of product		7.5.11
	Control of monitoring and measuring equipment		7.6
8.	**Measurement, analysis and improvement**	25 – 30	8.0
	General		8.1
	Monitoring and measurement		8.2
	Feedback		8.2.1
	Complaint handling		8.2.2

	Reporting to regulatory authorities		8.2.3
	Internal audit		8.2.4
	Monitoring and measurement of processes		8.2.5
	Monitoring and measurement of product		8.2.6
	Control of Nonconforming Product		8.3
	General		8.3.1
	Actions in response to nonconforming product detected before delivery		8.3.2
	Actions in response to nonconforming product detected after delivery		8.3.3
	Rework		8.3.4
	Analysis of data		8.4
	Improvement		8.5
	General		8.5.1
	Corrective action		8.5.2
	Preventive action		8.5.3
Annexure			
ANX–I	Glossary of terms	32	==========
ANX–II	Process flow chart	33 – 34	==========
ANX–III	Roles and Responsibility	35-37	==========
ANX–IV	Quality Objectives	38	
QM-001-01	Quality Policy		
QM-001-02	Organizational Chart		

(B) Authorization Statement

SEQUOIA HEALTHCARE is committed to establishment and maintenance of Quality Management System – Requirements and Requirements for regulatory purposes given in Quality Management System and implemented by the company to meet the requirements of ISO 13485:2016.

The members of **SEQUOIA HEALTHCARE** shall strictly adhere to the various procedures and work instructions / SOPs as supported by the policies outlined in Quality Management System.

Mr. Rajendra Patil has been appointed as **Management Representative** of **SEQUOIA HEALTHCARE.** He is responsible for ensuring compliance with the requirements stipulated in Quality Management System. He is authorized to ensure that the ISO 13485:2016 System is established, implemented, and maintained by the company. MD – Operation gives full support and cooperation to Management Representative for effective implementation of the System. **MR Coordinator** assumes the responsibilities of management representative in his absence.

Authorized by,

Managing Director

SEQUOIA HEALTHCARE

2.0 Company Profile

2.1 SEQUOIA HEALTHCARE

Sequoia Healthcare India is started by professionals with more than 25 years of experience in Radiology & Imaging Equipment and Accessories. Sequoia Healthcare is engaged in Refurbishing, Servicing & Installation of Medical Devices. We have been in this industry from the past 25 Years working with various MNCs in different geographies. We currently have strong teams based all over west, south & central India. We have sales team based in Dubai & Nairobi catering to Middle East & African Market.

SEQUOIA HEALTHCARE is having its head office in Bangalore and Sales & Marketing teams at all over India with state of art high speed machinery. We have in house Fabrication unit and quality management team that follows stringent quality control protocols throughout the process ranging from Refabricating to finished goods to ensure our products are reliable and effective in terms of safety.

At present, the Company has an efficient organization comprising a team of dedicated professional personnel in all areas of management. And yes, we never fail to match the delivery schedules and always believe in timely supply of Medical devices to our valued customers.

The key to our success is:

- Capacity to execute large orders;
- Quality matches customer requirements;
- Day-to-day implementation of directive requirements;
- Dedicated teamwork;
- Commitment to timely supply;
- Protection of environment;
- Compliance with regulatory requirements;
- Safety & Efficacy of Devices;

2.2 Scope of Certificate

Quality Management System is prepared as per guidelines of ISO 13485:2016 for Refurbishing, Servicing & Installation of Medical Devices, Sales & Distribution of Medical devices. The ISO 13485:2016 System has been implemented for:

System	Scope of certificate

2.3 Permissible exclusion

SEQUOIA HEALTHCARE working on activities such as Refurbishing, Servicing & Installation of Medical Devices so Design and Development does not apply and for that reason, this Clause is not applicable and excluded from MD-QMS.

2.4 Classification of products as per EU regulations

Product Name	Product description	Intended application	Classification
Inspiration 64 CT Scanner	This CT system is a diagnostic imaging device intended to produce images based on tissue density variations. The device can perform computer processing of X-ray signals that pass through the patient from multiple directions, and the cross-sectional image reconstructed can be used for diagnosis.	The Inspiration 64 Slice is intended to be used for whole-body computed tomography.	Class IIa
MRI Scanner (Clarity 1.5T)	MRI Scanners uses a large magnet and radio waves to look at organs and structures inside the body.	Clarity 1.5T is an MRI system that produces transversal, sagittal, coronal and oblique cross-section images of the internal structure of the whole body	Class IIa

3.0 Control and Distribution

3.1 **Structure of** Quality Management System

The Quality Management System is prepared according to the table of contents. All pages are given continuous numbering throughout the Quality Management System.

The Quality Management System is supported by documented MD-QMS System covering MD-QMS procedures and work instructions / SOPs or test procedures. In addition, a separate list of the

chapter-wise procedures referred in this Quality Management System is given in Annexure – I and a glossary of terms is given in Annexure – II.

The Quality Management System is issued in loose leaf and is accessible to the staff and customers.

The implementation of this Quality Management System and related MD-QMS and System procedures are mandatory for all departments. The changes made in this Quality Management System are effective through the document control procedure and must be approved by the authorized person.

3.2 Responsibility

The responsible person approves the front / cover page of the Quality Management System. The control and maintenance of Quality Management System is the responsibility of Management Representative who maintains master list of Quality Management System. When there are any changes / amendments, then the same page will be approved from the GM – Operation by Management Representative before issue of such changed / amended page to the concerned copy holder.

3.3 References

- ISO 13485:2016 Quality Management Systems – Requirements for Quality Management purposes
- QMS and System Procedures covering all procedures listed in Annexure – I.

3.4 Distribution

- Copies of Quality Management Systeml are distributed to the various departments on a “controlled” basis. Controlled copies are the one, which are subject to incorporation of "revisions.” Those in which the amendment is not reflected / communicated are known as "uncontrolled" copies.
- "Controlled" copies of the Quality Management System are stamped “Controlled Copy".
- Management Representative maintains Master list cum distribution list for issue of Quality Management System, and accordingly copies are distributed with copy number to copy holders.
- Amendments and revised pages of Quality Management System are issued by Management Representative through a "Change Note" to holders of controlled copies of the Quality Management System. Upon receipt of such revisions, the recipient will replace the pages by the revised ones.
- "Uncontrolled" copies may be issued by the Management Representative to the prospective customers and others on the request of the GM – Operation but the recipient shall not be issued the amendments / revisions.
- Management Representative is responsible to update amendment sheet in line with any amendment and all the information regarding revisions are distributed to copy holders.
- If any amendment due to change in page number is done then the table of contents is amended accordingly.

3.5 Numbering and Document Control for Quality Management System

- The number forQuality Management System is given as QMS 001, being first tier of documents of the quality management System.

- Quality Management System is divided into two sections – section 1 and 2. Section 1 deals with general information and has chapters numbered 1 to 3. Section 2 addresses the Quality Management System elements of ISO 13485:2016.
- When any revision becomes necessary, it is the affected page that is replaced and not the whole chapter. In such case revision is reflected by changing suffix of issue no. and the same is recorded on the amendment record sheet of the Quality Management System. Initially issue no. is considered as 1.0 and if total Quality Management System is revised then issue no. is changed to issue no. 01. For any page wise amendment, issue number of the page is changed to 1.1 for page wise revision. Total nine amendments are possible in single page of single chapter. If it crosses nine amendments then whole issue of Quality Management System is changed to next no. i.e. 1.0 becomes 01 and so on. All such amendments are recorded in the Amendment Record Sheet given in the paragraph 3.6.

3.6 Amendment Record Sheet

Amd. No.	Chapter no.	Page no.	Replace current issue no.	New issue no.	New issue date	Reason for change	Signature of copy holder

Note :-

- All the pages other than those listed above are currently in the Issue Number 1.0. If any changes are done then the next issue no. is given by suffix to that page (say for example 2.1) and is recorded on the page listed above.
- To check the validity of the complete Quality Management System, confirm current issue status of this page with Management Representative and crosscheck with sheets changed.

4.0 Quality Management System –Requirements for Regulatory Purposes

4.1 General Requirements

SEQUOIA HEALTHCARE has established, documented, implemented, and maintained a Quality Management System and continually improved its effectiveness in accordance with the requirements of ISO 13485:2016.

a). Critical processes needed for the MD-QMS and their application throughout the organization are identified and listed in the Process Flow (Annexure – III), department wise Process Approach, for the refurbishing, Servicing & installation in related SOPs.

b). The sequence and interaction of processes is determined and is given in the Annexure–III

c). The criteria and methods needed to ensure effectiveness of operation and control of processes are determined, established, and monitored through Quality Objectives.

d). Necessary resources and information are available to support operation and monitoring of the processes.

e). The processes are monitored, measured, and analyzed.

f). The necessary actions are implemented to achieve planned results and continual improvement of these processes.

g). The risk-based approach to the control of the appropriate processes needed for the quality management System is applied.

h). The records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements are established and maintained.

Any changes to the processes based on this standard and other applicable requirement are:

- Evaluated for their impact on the Quality management System;
- Evaluated for their impact on the medical devices refurbished, serviced & installed under this Quality management System;
- Controlled in accordance with the requirements of this standard and regulatory requirements.

All these processes are managed in accordance with requirements of ISO 13485:2016 and related regulatory requirements.

At present, no critical processes are outsourced. But if any critical process will be done by outside party (due to any emergency or non-availability of resources at our end) then that process will be controlled by the defined process or through incoming inspection. Also, necessary document covering defined process for follow-up will be given to the subcontractor(s) to establish control.

The verification of such outsourced product/process is planned and maintained as per purchase process (Reference: Clause No 7.4.2)

Documented procedures for the validation of the application of computer software used in the quality management System are established and they are validated prior to initial use and as and when any changes happen in software or application.

The specific approach and activities associated with software validation and revalidation is considered based on the risk associated. Records for the software validation are maintained accordingly.

4.2 Documentation Requirements

4.2.1 General

The written documents are prepared in **SEQUOIA HEALTHCARE** as per list given below considering the size of organization, type of activities, the complexity of processes and their interactions and the competence of personnel.

a.) Documented statement of Quality Policy and Quality Objectives
b.) Quality Manual

c.) System Procedures
d.) Work Instructions, SOPs, and Exhibits to ensure the effective planning, operation, and control of processes
e.) Formats (blank formats to fill in details of routine work, which becomes records later on and considered as an objective evidence of activity being performed),
f.) Documents required to be maintained as a part of national and regional regulatory requirements.

4.2.2 Quality Manual

Quality Manual is prepared, having details of:

a.) The scope of the quality management System (organization activities), including details of and justification for exclusion related to clause no. 7.3
b.) The documented procedures established for the quality management System, and reference of the procedure at the end of each chapter,
c.) Description of the interaction between the processes of the quality management System.

Quality Manual outlines the scope, structure, and general principles of the operation of Quality Management System and serves as a declaration of the intentions of the GM – Operation to satisfy various clauses of ISO 13485:2016. Each chapter gives details for ISO 13485:2016 requirements, sequence, and interaction of the processes included in the Quality Management System. The structure of documentation is as below:

Tier	Name of documents
Top	**Quality Policy**, which gives the intention of Top Management to fulfill the requirements of the standard.
1st tier	**Quality Manual**, which gives details of fulfillment of requirements of ISO 13485.
2nd tier	**Quality Procedure**, which gives step-by-step implementation of the requirement of ISO 13485 and as per the mandatory procedure requirements of the above standards.
3rd tier	**Work Instruction, Process Flow Chart (Process Approach), Standard Operating Procedure, Exhibit and other reference documents**, which give step-by-step implementation of the particular requirement of department, product, quality assurance as well as legislation.
4th tier	**Formats,** which give guidance to maintain data in standardized way and forms a part of records (Once filled) and are considered as an objective evidence of the activities or process carried out.

4.2.3 Medical Device File

For each medical device type or medical device family, the organization establishes and maintains one or more files, either containing or referencing documents generated to demonstrate conformity to the requirement of ISO 13485:2016 standard and compliance with applicable regulatory requirements.

The contents of the file(s) include, but are not limited to:

i. General description of the medical device, intended use/purpose, and labeling, including any instructions for use;

ii. Specifications for product;

iii. Specifications or procedures for Refurbishing, packaging, storage, handling and distribution;

iv. Procedures for measuring and monitoring;

v. Requirements for installation;

vi. Procedures for servicing

4.2.4 Control of Documents

All the documents, including records related to the Quality Management System requirements, are controlled as per documented procedure.

A) They are reviewed for adequacy and are approved by authorized person(s) as per documented procedure.

B) The respective Functional Heads / Management Representative ensure that the latest versions of applicable documents are available at the point of use.

C) All the controlled documents have been identified, legible and made readily available at their point of use.

D) Management Representative ensures that all external documents needed for use in MD-QMS are identified and proper control is established. Similar controls are also applied to the external documents necessary for the planning and operation of Quality Management System, like standards, customer data and documents of external origin. The external documents are identified and their distribution is controlled.

E) All the documents are maintained properly to prevent deterioration or loss of documents

F) Master list of document with current revision of documents (latest issue number) and distribution list of all the documents is maintained for all the four tiers of documents to prevent unintended use of obsolete documents. If any obsolete documents are kept for future reference, then stamp of **"Obsolete Copy"** is put on the document.

Changes to the documents are approved by the same authority as per the details given in the procedure. In case of non-availability of designated approving authority for a longer period, the other authorized person having pertinent background of the process / product / System will approve the same.

All **obsolete documents** are retained for at least **3 years**. This period ensures that documents according to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device (as the shelf life of such medical device is 2 years).

4.2.5 Control of Records

All records, which are generated to provide evidence of conformity to the requirements in various areas, inclusive of those received as "Test Certificates or Calibration Certificates", are maintained to demonstrate the effective operation of the Quality Management System and are controlled. The records are kept legible, readily identifiable, and retrievable.

Procedure is established and maintained to define the controls needed for identification, storage, protection, retrieval, retention and disposition of records.

Quality Management System records are stored in such a manner as to ensure safe preservation and easy retrieval, and protected against damage, deterioration, or loss. The System is applicable for hard copy of records as well as records maintained in electronic media. All the records are properly identified and controlled.

Each Functional Head maintains a list of records including retention time for the records being maintained in his department. Record remains legible, identifiable and retrievable to the activity, product or service involved.

Product related records, such as Refurbishing, serving, installation Records, Test Reports, etc., are retained for at least **3 Years** from the date of delivery of the products from the Company based on the product requirements as well as regulatory requirements. Shelf life of the products covered under the scope is **2 Years**.

4.2.5 Related Procedure

- Procedure for document and data control.
- Procedure for control of records.

5.0 Management Responsibility

5.1 Management Commitment

GM – Operation provides evidence of company's commitment to the development and implementation of the Quality Management System and continually improving its effectiveness as below:

a.) The importance of meeting customer as well as regulatory and legal requirement is communicated across the company. Such requirements are identified, documented, and provided for follow-up to the concerned Functional Heads.

b.) The Quality Policy is established, documented and provided for ready reference to the employees.

c.) Quality Objectives are established.

d.) At least once in **a year** management review (Internal audit) is conducted for review of activities and is attended by GM – Operation.

e.) **Company** has identified resource requirements and has provided adequate in-house resources in terms of qualified personnel, test equipment and facility for refurbishing and testing as well as maintaining clean process area to ensure safety of the medical devices. GM – Operation is responsible for providing appropriate resources and trained personnel for effective implementation of the Quality Management System in the company.

5.2 Customer Focus

Based on routine review of contract documents as well as communication and customer survey, the customer needs and expectations are determined and documented. All these data are processed and converted into customer requirements and conveyed to the concerned person. While preparing customer requirements, consideration is given to obligations related to product as well as regulatory

and legal requirements. GM – Operation ensures that customer needs and expectations are determined and customer requirements are fulfilled for enhancing customer satisfaction.

5.3 Quality Policy

Quality Policy is prepared and is given in QM-001-01 to this Quality Management System. Quality Policy is signed by the **Director** and Quality Objectives are identified / framed based on Quality Policy. This Quality Policy:

a.) Is appropriate, considering the purpose of the company;

b.) Includes a commitment to comply with requirements and to maintain the effectiveness of the quality management System;

c.) Provides a framework for establishing and reviewing quality objectives;

d.) Is communicated (by displaying the same at prime locations within the organization) and understood within the organization; and

e.) Reviewed for continuing suitability, during management review meeting.

Further, process wise Quality Objectives (Control Parameters) are identified and are recorded in related records.

Quality Policy Implementation

All the employees are advised to undergo Quality Policy Training on joining the company. Implementation of the Quality Management System and the Quality Policy on a day-to-day basis is responsibility of the Management Representative and it is achieved by ensuring that the respective employees understand the Quality Policy and comply with the Quality Management System documents. The Quality Policy is reviewed in management review meeting **once in six months** for continual improvement in the effectiveness of the Quality Management System. Quality Policy is controlled by effective date of implementation.

5.4 Planning

5.4.1 Quality Objectives

Quantifiable Quality Objectives are established at relevant functions, based on documented Quality Policy. Quality Objectives are consistent with the Quality Policy and meet product and customer requirements. The quantifiable criteria are dynamic and reviewed in management review meeting for our commitment to continual improvement.

5.4.2 Quality Management System Planning

The resources needed to achieve the Quality Objectives are identified, discussed in the management review meeting and planned. The resource planning is documented. GM – Operation ensures that planning of the QMS is carried out in line with ISO 13485:2016 requirements and Quality Objectives.

Top Management ensures that:

a.) The planning of the quality management System is carried out in order to meet the requirements as stated as well as to fulfill the requirements of Quality Objectives;

b.) The integrity of the quality management System is maintained when changes to the quality management System are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

(a.) GM – Operation has defined responsibilities, authorities and their interrelation for all the persons and communicated within the organization. All staff members are responsible for maintaining the quality of their own work and for informing their Respective Heads any conditions, which are adverse to the quality of the work being produced or adverse to the satisfactory operation of the Quality Management System.

(b.) Personnel at various levels in **Company** are responsible and have the authority within their defined areas of control for:

- The quality of work carried out;
- Initiating action to prevent the occurrence of product non-conformance;
- Identifying and recording quality problems;
- Initiating, recommending and providing solutions to quality problems;
- Verifying the effectiveness of the solutions.
- Controlling further processing until all conditions are satisfactory.

The organization chart of the Company, showing the interrelation of all the personnel who manage, perform and verify the work ensuring quality, is given in Annexure–IV.

(c.) Authority and responsibility for all the concerned persons is documented in job description and communicated to them in order to facilitate effective Quality Management System. The copies of job description and specifications are given to the concerned persons.

(d.) In case of vacancy / absenteeism, the delegation of authority shall be upwards and responsibility shall go downwards, unless otherwise specified in the documents.

(e.) Specific personnel are also deputed in QA department as per the regulatory requirements considering the nature of the organization.

5.5.2 Management Representative

GM – Operation has appointed a **QA Executive** as a Management Representative for the company as shown in the Organization Structure. Apart from other duties, he has been given the authority for ensuring establishment, implementation and maintenance of the Quality Management System in accordance with ISO 13485:2016 requirements and System laid down for the company, and working as Management Representative.

The authority and responsibility of Management Representative include:

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, and

c.) Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.

Management Representative keeps liaison with the ISO 13485:2016 certifying body for all matters related to the QMS. Designated **MR Coordinator** assumes the responsibilities and authorities as Management Representative during his absence.

5.5.3 Internal Communication

The organization ensures communication between Functional Heads and various levels of employees regarding the processes of the quality management System and their effectiveness.

5.6 Management Review

5.6.1 The Quality Management System established in the **Company** is Systematically reviewed for its continuous suitability and effectiveness in confirming the requirements of ISO 13485:2016. The review includes implementation of Quality Policy and Objectives, identifying any areas which require improvement, and evaluating need for changes for effective functioning of the System.

This review is carried out at least once in **Six Months by GM – Operation** or his nominee by holding Management Review Meetings, which are attended by Management Representative and all Functional Heads. It is the responsibility of the Management Representative to prepare the agenda and minutes of management review meeting covering the following details:

- Discussion held;
- Action planned;
- Target date of completion for planned actions;
- Person responsible to complete planned actions.

5.6.2 Review Input

Input to management review includes current performance and improvement opportunities related to the items listed hereunder:

a.) Action decided in the previous meeting,
b.) Effectiveness of System in achieving Quality Objectives,
c.) Requirements for resources and training needs,
d.) Results of internal / external audit,
e.) Customer's complaints / feedback,
f.) Suitability of Quality Policy and need for changes if any
g.) Process performance and product conformities,
h.) Status of corrective and preventive action,
i.) New / revised regulatory requirements,
j.) Reporting to regulatory authorities,
k.) Changes brought in technology, product mix, market, engineering change, etc. that affects QMS, if any.
l.) Specific issue (if any) for effectiveness and basis for improvement of the quality management System and recommendation for improvement,
m.) Continuing suitability of the QMS in relation to changing circumstances and commitment to continual improvement.

5.6.3 Review Output

Based on management review process, actions emerged for any of the items related to:

a.) Improvement of the effectiveness of the quality management System and its processes;
b.) Improvement of the product according to customer requirements;
c.) Changes needed to respond to applicable new or revised regulatory requirements;

d.) Need for resources.

5.7 Related Procedure

- Procedure for Management review

6.0 Resource Management

6.1 Provision of Resources

SEQUOIA HEALTHCARE has identified resource requirements and provides timely resources in terms of qualified personnel, test equipment and facility for Refurbishing and testing. The resources are provided considering:

a). Implementation and maintenance of quality management System and continually improving its effectiveness, and

b). Enhancing customer satisfaction by meeting regulatory and customer requirements.

Adequacies of these resources are reviewed, for example, during:

- Management review;
- Contract review;
- Legal compliance review;
- Internal audit results; and
- Customer complaint review.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirement are suitably trained and / or experienced. Their work competence is checked based on applicable education, training, skills and experience.

6.2.2 Competence, Awareness and Training

The organization has established a procedure for training needs assessment and for providing appropriate training to specified needs. All personnel whose work affects the conformity of product requirement and legal requirements are made competent based on performance review and on-the-job training is provided for upgrading their knowledge and achieving the necessary competence. During routine work, due to change in area of work or any other reason, the training needs are identified and provided. Functional Head ensures that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives. Top Management ensures that the necessary competence has been achieved.

Suitable quality management System awareness programs are arranged for all the employees of the company to ensure that the requirements are well understood at all levels.

In training procedure, considerations are taken for satisfying the needs of the organization, responsibility and ability of personnel, as well as risk related to medical device. Necessary training programs on quality matters and safety of medical devices are planned and implemented. The training procedure and process approach incorporates:

a). Determining necessary competence for personnel performing work affecting conformity to product requirements;

b). Providing training or other actions to achieve necessary competence;

c). Evaluating the effectiveness of actions taken;

d). Ensuring that the personnel are aware of the relevance and importance of their activities and their contribution to achievement of the Quality Objectives;

e). Maintaining appropriate records of education, training, skills and experience.

6.3 Infrastructure

Appropriate facilities are identified, provided and maintained to achieve conformity of product requirements. Infrastructure includes:

a). Building, workspace and associated utilities,

b). Process equipment (both hardware and software), and

c). Supporting services (such as transport, installation etc.,).

Preventive Maintenance activities for the equipment as well as identified infrastructure (such as cleaning of the area, painting, repairing, etc.) are documented and are carried out on monthly, annual or need basis.

Records of such maintenance are maintained to show evidence of compliance with the maintenance schedule.

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

Appropriate work environment is identified to achieve conformity of product and provided considering identified factors related to medical devices. Following requirements are applied as a compliance with the work environment;

a). SOP is established, implemented, and documented for health of employees, cleanliness, and clothing of personnel, considering the contact between such personnel and the product or work environment could adversely affect the quality of the product.

b). 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 and records for such training etc. are maintained.

6.4.2 Contamination Control

The contamination control is defined, planned, and maintained using documented arrangements. Documented arrangements in this context are a documented set of activities or operations organized or classified in a logical order or sense that ensure that clean conditions of the work environment are preserved and contamination is prevented: standard operating procedures, instructions, supplier instructions, planned controls, forms, checklists, and their evidence.

6.5 Related Procedure

- Process Approach – Training
- Procedure for training
- Procedure for control and monitoring of work environment

7.0 Product Realization

7.1 Planning of Product Realization

Planning for sequence of processes and sub processes is consistent with the MD-QMS requirements of **SEQUOIA HEALTHCARE** and documented in the Quality Plan / Process Approach / SOPs / Work Instruction documents. The process flow chart of **SEQUOIA HEALTHCARE** is given in Annexure III of this Quality Management System.

In planning process for realization of product, **SEQUOIA HEALTHCARE** has determined the following, as appropriate:

a). Quality objectives and requirements for the product;
b). Need to establish documents and process and provide resources specific to the product;
c). Required verification, validation, monitoring, measurements, inspection, and test activities specific to the product and the criteria for product acceptance;
d). The records those are necessary to provide confidence of conformity of the processes and resulting product to fulfill requirements.

The output of this planning is maintained in the form of product specifications, product brochure, quality plan, etc.

Risk management is identified and documented throughout product realization as per the requirements given in the ISO 14971. Record of risk management is maintained and is communicated to all concerned throughout the **Company.**

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Products

The company receives customer orders (verbal / written) and requirements are determined clearly. In **SEQUOIA HEALTHCARE,** customer requirements are determined including:

a). Product requirements specified by the customer, including the requirements for availability, delivery and post delivery activities;
b). Product requirements not specified by the customer but necessary for intended or specified use;
c). Obligations applicable to product, including legal and regulatory requirements;
d). User training needed to ensure the specified performance and safe use of the medical device;
e). Any additional requirements considered necessary by the organization.

Post delivery activity, including action under warranty provisions, contractual obligations such as recall of expired medical devices etc., and supplementary services such as recycling or final disposal of products are communicated and followed.

7.2.2 Review of Requirements Related to the Products

A) As soon as customer inquiries are received for their requirement, it is reviewed to ensure that customer's requirements are clearly identified, understood, and whether they can be met. If customer provides no documented statement of the requirements then customer requirements are confirmed before acceptance. Matters that are not clear, including contract / order requirements previously expressed, are resolved with the customer. Normally, customers understand product by name; generic name, packing, qty., delivery and specifications are conveyed in their documents or verbally.

B) The internal contract review is carried out as described in Process Approach to assess capability for supply of the product and to meet product requirements. In case there is any difference in the specifications of the customer then it can be resolved by carrying out the changes as required by the customer.

C) Prior to commitment to supply a product to the customer, customer orders (written / verbal) are reviewed to ensure that:

- Customer requirements are clearly documented;
- Any variation from the contract is resolved; and
- **SEQUOIA HEALTHCARE** can meet all contractual requirements.

D) **Amendment to a order**

Subsequent contract variations are documented and subjected to similar review. Any amendment to the contract is identified and confirmed with the customer. It is conveyed to the concerned person for changed requirements as per details given in procedure.

E) All the documents/records related to order are maintained and reviewed through

7.2.3 **Customer Communication**

SEQUOIA HEALTHCARE has identified and implemented arrangements for communication with customers related to:

a). Product information;
b). Enquiries, contracts or order handling, including amendments;
c). Customer feedback, including customer complaints; and
d). Advisory notices.

The organization communicates with regulatory authorities in accordance with applicable regulatory requirements

7.3 **Designs and Development**

SEQUOIA HEALTHCARE is work of activities Refurbishing, Servicing & Installation of Medical Devices. So, Design and Development does not apply and for that reason this clause is not applicable and excluded from the MD-QMS.

7.4 **Purchasing**

7.4.1 **Purchasing Process**

Procedure is established and implemented for purchasing of materials and services to ensure that the purchased products meet the specified purchase requirements.

The type and extent of control are dependent on quality of the final product and such controls are applied on the supplier to ensure conformity of the final product as well as process of the product realization.

The System for selection and evaluation of suppliers / subcontractors has been established on the basis of their ability to supply product in accordance with company's requirements as well as follow-up with the regulatory requirements. The records are maintained in the form of Approved Vendors List for all the different categories of purchases as well as results of evaluations and follow-up actions. Approved Vendor List is updated **once in a year** based on vendor rating (re–evaluation of supplier).

7.4.2 **Purchasing Information**

Purchasing information describes the product to be purchased, including:

a). Product specifications;

b). Requirements for approval of product, procedures, processes and equipment;

c). Requirements for qualification of personnel; and

d). Quality Management System requirements.

The purchase documents contain data which includes any items described below:

- Reference of specifications, requirements for approval or qualification of product, procedures, processes, equipment and personnel;
- The clear description with relevant specification / reference of standards, wherever applicable, and any other information given in the purchase documents.

Authorized person as per procedure reviews the purchase document for adequacy of details, quantity, and description of goods, as applicable, prior to release and approval. Company ensures that purchasing data is clearly written in the purchasing documents to avoid ambiguity and is correctly understood prior to its communication to the subcontractors / suppliers.

Suppliers of active raw materials are identified and instructed to maintain traceability. The details of requirements of traceability and maintenance of documents and records to establish the traceability are communicated to suppliers as a purchasing data. Records of such information are maintained in Purchase Order.

7.4.3 Verification of Purchased Products

Quality Plan / Inspection and Test Plan / Critical Specifications Sheet are prepared for the incoming inspection and testing of the products. The Quality Control department collects the sample upon receipt of materials and carries out necessary inspection and testing as per the requirements given in the Quality Plan / Inspection and Test Plan / Critical Specifications Sheet. All such information is provided to the customer as purchasing information in the purchasing document as a method of product approval.

Normally, customers do not ask to verify purchased product at subcontractor / supplier's premises as well as SEQUOIA HEALTHCARE does not inspect product at subcontractor's / supplier's premises. But in future, if customer or SEQUOIA HEALTHCARE proposes to perform verification activities at the subcontractor's / supplier's premises then suitable arrangement will be done at subcontractor's / supplier's place and method of product release will be conveyed to supplier / subcontractor as a part of purchasing information.

Records of such verification of purchased products are maintained.

7.5 Refurbishing and Service Provision

7.5.1 Control of Refurbishing and Service Provision

The organization controls refurbishing and service operation through:

a. The availability of information that specifies the characteristics of the product;
b. Documented procedures / work instructions / SOPs / reference measurement procedures / Process Control Parameters are made to define the manner of refurbishing, approval of process, monitoring and control of suitable process;
c. As per established maintenance System, maintenance of equipment for refurbishing and service operation is done and records are maintained to ensure use of suitable equipment;

d. On the process control and utility equipment appropriate measuring and test equipment / instrument, etc. capable of providing necessary accuracy and precision are used at the work places;
e. The criteria for workmanship and implementation of monitoring and measurement of process are defined and documented;
f. The implementation of medical devices release, delivery and post delivery activities; and
g. The implementation of defined operations for labeling and packaging.

Records are prepared and maintained for each batch of medical devices that provide traceability as specified in further section and identify the quantity of medical device manufactured and quantity of medical device approved for distribution.

7.5.2 Cleanliness of products

SOP for the cleanliness of the product and/or contamination control is defined. The organization documents the requirements for cleanliness of product or contamination control of product if:

a) Product is cleaned by the organization;

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

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

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

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

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

7.5.3 Installation activities

Detailed procedures for the medical device installation and acceptance criteria for verification of installation will be defined.

If the agreed customer requirements will allow installation of the medical device to be performed by an external party other than the company or its supplier, the same will be defined in the documented procedure for medical device installation and verification.

Records of medical device installation and verification of installation performed by the company or its supplier will be maintained.

7.5.4 Servicing activities

If servicing of the medical device is a specified requirement, the company will ensure that documented procedures for the servicing requirements, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.

Detailed records for the servicing are maintained:

a) To determine if the information is to be handled as a complaint;

b) For input to the improvement process.

Records of servicing activities carried out by the company or its supplier is maintained in the prescribed format and used for the improvement of the process.

7.5.5 Particular requirements for sterile medical devices

Not Applicable

7.5.6 Validation of Processes for Refurbishing and Service Provision

Procedure for validation is established, implemented and documented for the validation of the identified processes. Also, necessary control on the validation of the application of computer software used is established. In case of changes, same validation procedure is established.

Records of validation are maintained.

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier Systems

Not Applicable

7.5.8 Identification

All products within the organization are identified by suitable means throughout product realization. Procedure is established, implemented, and documented for such product identification.

Procedure for product identification is also having System to ensure that medical devices returned to the company are identified and distinguished from conforming product.

All products, from the time of receipt until dispatch is identified by one or more of the following:

- Type, name, batch no. / lot no., specification, brand name and other precise identification, as applicable;
- Brand name, etc.;
- Self identification;
- Others, as applicable.

7.5.9 Traceability

7.5.9.1 General

A procedure is established, implemented and documented for traceability of medical device. This procedure includes the extent of product traceability and the records identified and maintained to ensure traceability of the medical device.

7.5.9.2 Particular requirements for active implantable medical devices and implantable medical devices

The products manufactured by **SEQUOIA HEALTHCARE** are not covered in the category of active implantable medical devices or implantable medical devices, hence the requirements of this clause are not applicable to the company.

7.5.10 Customer Property

Company exercises proper care with the customer property, while it is under the company's control or during processing. Company has identified, verified, protected and safeguarded customer property for use or incorporation into the product. If any customer property is lost, damaged or otherwise found unsuitable for use, Company reports this to the customer and maintains records for the same. The process is followed as below:

- Customer property like, material for packing / marking / manufacturing is received by the company for inclusion in the order requirements;

- Such materials are checked as per the Quality Plan. All the acceptance criteria of the received material are considered as per defined specifications, if not provided by the customer;
- After necessary inspection and testing the accepted customer properties are Systematically stored in the stores with due care. Such customer properties are identified by the name of customer with detailed specifications. No further inspection or tests are performed unless otherwise specified in the contract specifications. Customer properties from receipt onwards are treated as per the routine process and are controlled according to the requirements. Any product that is damaged, lost, non-conforming or otherwise unsuitable for use is recorded and reported to the customer.

  Verification by the customer does not absolve **SEQUOIA HEALTHCARE** of the responsibility to provide an acceptable product.

7.5.11 Preservation of Products

Procedure is established, implemented, and documented for preserving the conformity of product during internal processing and delivery to the intended destination.

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

A procedure is established, implemented, and documented for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions are controlled and recorded.

7.6 Control of Measuring and Monitoring Equipment

SEQUOIA HEALTHCARE has determined the monitoring and measurement to be undertaken during the processes and products and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. Appropriate inspection, measuring and test equipment / instruments / software etc. capable of necessary accuracy and precision are used at the workplaces to assure conformity of product to specified requirements.

SEQUOIA HEALTHCARE has established, implemented and documented procedure to ensure that monitoring and measurement are carried out in a manner that is consistent with the monitoring and measurement requirements. Equipment/instruments are calibrated at regular intervals and the acceptance criteria is established on the basis of stability, purpose and usage, thereby ensuring that it is capable of getting the necessary accuracy and measurement requirements.

SEQUOIA HEALTHCARE ensures valid results of the processes and products through measuring and monitoring equipment. The instruments are:

a). Calibrated or verified, or both, at specified intervals (as per procedure) or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standard exists, the basis used for calibration or verification is recorded;

b). Adjusted or re-adjusted, as necessary;

c). Identified to determine its calibration status;

d). Safeguarded from adjustment that would invalidate the measurement results;

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

Equipment used in the company is selected based on capability, accuracy and precision of the measurement required to be made to ensure quality. The instruments are calibrated and adjusted

at regular intervals as per schedules or prior to use, and recorded. All the critical equipments are calibrated against certified equipment having a known valid relationship to nationally / internationally recognized standard.

The equipment used for monitoring and measurement is also included for calibration / verification as per established System, and record is maintained. Also, computer software used to satisfy intended application is included, and verification as well as configuration management of computer software (where it is used to monitor and measure) is done periodically.

The company assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The company takes appropriate action on the equipment and any product affected. Procedures are established and details are given for calibration methods, frequency, identification System, etc. Calibration status of the equipment is identified by stickers / tags / records to recall when calibration is due. Equipment is handled in a manner to avoid damage and deterioration during handling, maintenance, and storage. Trained persons handle the equipment to ensure the validity of calibration. The measuring and monitoring equipment are safeguarded to eliminate the possibility of invalidation of the calibration or are subjected to calibration before use.

New or repaired equipment and equipment used for inspection are subjected to an initial inspection for accuracy or are proven prior to release for use in testing.

Records of the results of calibration and verification done by outside agency as well as calibration or verification done in-house are maintained.

7.7 Related Procedure

- Procedure for control of monitoring and measuring equipment
- Procedure for purchasing
- Procedure for identification
- Procedure for traceability
- Procedure for preservation
- Process Approach – Marketing
- Process Approach – Refurbishing
- Process Approach – Stores
- Process Approach – Engineering
- Process Approach – Dispatch

8.0 Measurement, Analysis, and Improvement

8.1 General

The quality plan is prepared and implemented to meet quality requirements and identify measurement and monitoring activities needed to assure conformity and achieve improvement. This includes need and use of applicable methodologies, including statistical techniques and extent of their use. The details of different stages of inspection, acceptance criteria, sample size, etc., are given in quality plan and followed by the company. Various records like list of equipment, skilled persons etc. are reviewed, and the compatibility of facilities (including documents) is ensured by the Management Representative to achieve the required quality at planning stage. SEQUOIA HEALTHCARE has planned and implemented the monitoring, measurement, analysis, and improvement processes needed:

a). To demonstrate conformity to product requirements;
b). To ensure conformity of Quality Management System; and
c). To maintain and continually improve the effectiveness of Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the performance of the quality management System, SEQUOIA HEALTHCARE monitors information related to meeting the customer requirements.

The method for obtaining and using this information is given as below.

Procedure is established, implemented and documented for collection of customer feedback, to provide early warning of quality problems, and for input into the corrective and preventive action processes.

At regular intervals, customer survey is taken to collect information on customer satisfaction. Such information is analyzed to measure satisfaction levels of customer and discussed in the Management Review Meeting. Information on customer satisfaction is also collected from the contract review records as a part of routine activities.

Customer perception includes collecting input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer / distributor's reports.

8.2.2 Complaint handling

Documented process approach for the customer complaint handling is prepared to resolve the complaints considering applicable regulatory requirements. The procedure includes:

a) Receiving and recording information;

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

c) Investigating complaints;

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

e) Handling of complaint-related product;

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

If any complaint is not investigated, justifications are documented. Any correction or corrective actions resulting from the complaint handling process are documented.

If an investigation determines activities outside the company contributed to the complaint, relevant Information are exchanged between the company and the external party involved.

Records of the customer complaints are prepared in the prescribed format and are used for the improvement of the System and achieving customer satisfaction.

8.2.3 Reporting to regulatory authorities

Documented procedure for reporting the regulatory requirements which require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, are prepared and followed.

Records of reporting to regulatory authorities are maintained in communication register.

8.2.4 Internal Audit

SEQUOIA HEALTHCARE conducts internal audit at least **once in one year** to determine whether the Quality Management System:

a). Conforms to the planned arrangements of the requirements of ISO 13485:2016. and to the Quality Management System requirements established by the company,

b). Is effectively implemented and maintained.

The internal audit is scheduled in the company on the basis of the status and importance of activity to be audited and previous audit results. Management Representative prepares the audit plan covering scope, schedule and other details. Personnel are nominated as auditors and provided audit training. It is ensured that the auditors are independent of the specific activities or areas being audited by them.

Procedure is established and maintained to define the responsibilities and requirements for planning and conducting audits, establishing records, and reporting the results.

The auditors verify implementation of documented Quality Management System and perform objective evaluation of the organization structure, procedures, working practices, resources, accuracy of the work, records, etc. The detailed System for planning and implementing audit to determine effectiveness of the quality is given in the procedure.

Records of the audits and their results are maintained.

Audit Report and Follow-up

The Auditor prepares nonconformity report on completion of the audit and the nonconformity is brought to the notice of auditee. They discuss about the appropriate actions to be taken and schedule for implementation in respect of any non–conformance observed. Audit findings are recorded and used as the main formal means of resolving problems and deficiencies detected in the Quality Management System. The copies of such NC reports are given to auditee after taking timely corrective action on NC reports, the auditee calls auditor to verify it and to close the NCR. During next audit, implementation and effectiveness of the corrective action taken on NCR is reviewed and recorded.

All the audit findings and verification of audit results are reported to the GM – Operation for review and evaluation of the System and taking corrective actions.

8.2.5 Monitoring and Measurement of Processes

Processes have been documented and implemented for monitoring and measurement of actual performance against the MD-QMS performance requirements on regular basis. These procedures provide quantitative as well as qualitative measures to meet company's need as well as monitor the key characteristics of operations. This includes the information for monitoring performance and conformity to the objectives and targets as well as evaluation of compliance with relevant MD-QMS and regulatory requirements as per documented procedures. The proactive measures are taken to monitor compliance with the QMS management program and operational criteria.

Results of analysis are recorded to track performance, relevant process controls and conformance with the quality objectives and targets.

The results are analyzed to determine the areas of success and to identify areas requiring corrective action and improvement on the basis of performance indicators, which have been laid down in the relevant MD-QMS management programs.

8.2.6 Measurement and Monitoring of Product

SEQUOIA HEALTHCARE monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements and documented procedures for inspection and testing.

Quality Plan has been established for ensuring that none of the incoming, in-process, and final stage products is issued before it has been verified for conformity of specified requirements. The amount and extent of inspection is determined on the basis of recorded evidence of their past performance. Evidence of conformity with the acceptance criteria is recorded in the inspection and test records along with authorized person's signature for release of products for delivery to customer.

None of the products are dispatched until all the testing activities specified in Quality Plan are completed and authorized person verifies test records. Documentary evidence in the form of records is maintained at all stages of inspection / verifications to ensure that the products are inspected as per Quality Plan and passes through the inspection tests with the desired acceptance criteria.

Records are maintained for the personnel performing inspection or testing. Detailed skill matrix is prepared and is used as a routine practice.

8.3 Control of Nonconforming Product

8.3.1 General

Company ensures that product which does not conform to specific product requirements is identified and controlled to prevent its unintended use or delivery. The detailed procedure is established to define the controls and related responsibilities and authorities for dealing with non-conforming product. The procedure includes identification, documentation, evaluation, segregation and disposition of nonconforming incoming, in-process and the final product.

The evaluation of nonconformity includes a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions, are maintained.

8.3.2 Actions in response to nonconforming product detected before delivery

Nonconforming product is dealt as below considering the nature of nonconformity:

a.) By taking action to eliminate the detected nonconformity (such as re-process etc.),

b.) By authorizing its use, release or acceptance under concession;

c.) By taking action to preclude its original intended use or application.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

When non-conforming product is corrected, then the corrected product is verified as per the procedure for inspection and testing and is passed through all the tests as specified in the Quality Plan.

8.3.3 Actions in response to nonconforming product detected after delivery

When non-conforming product is detected after delivery or its use has started, SEQUOIA HEALTHCARE takes action appropriate to the effects, or potential effects, of the nonconformity.

This procedure covers the issuing of advisory notices in accordance with applicable regulatory requirements. This procedure is capable of being monitored any time and tested once in a year.

Records of rework are maintained.

8.3.4 Rework

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

Records of the nature of nonconformity and any subsequent actions taken, including concessions obtained are maintained.

8.4 Analysis of Data

Procedure is established, implemented, and documented to determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management System and to evaluate improvement in the effectiveness of the quality management System.

Company has defined a process to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and for evaluating continual improvement of the effectiveness of Quality Management System. The data generated during measuring and monitoring activities and other relevant sources are analyzed to provide information on:

a). Feedback (complaint and feedback);
b). Conformity to product requirements;
c). Characteristics and trends of processes and products, including opportunities for preventive action;
d). Suppliers' performance and evaluation:
e). Audits; and
f). Service reports.

Records of analysis of above data are maintained.

8.5 Improvement

8.5.1 General

SEQUOIA HEALTHCARE will identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management System and safety of medical devices and performance through quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 Corrective Actions

SEQUOIA HEALTHCARE takes actions to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are reviewed to ensure their appropriateness to the effects of the nonconformities encountered.

The procedure is documented for corrective action, which includes:

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). planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;

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

f). Reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken are maintained in prescribed format of corrective action report.

8.5.3 Preventive Actions

The preventive action appropriate to the effects of the potential problems is identified to eliminate the causes of potential nonconformities to prevent occurrence.

The procedure is documented for preventive action, which includes:

a). Determining potential nonconformities and their causes;

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

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

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

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

Records of the results of any investigation and of action taken are maintained in prescribed format of corrective action report.

Records

The records of handling customer complaints and various records of corrective and preventive actions are maintained. The records of corrective and preventive actions taken are submitted to the management for their review.

8.6 Related Procedure

- Procedure for customer feedback
- Procedure for internal audit.
- Procedure for monitoring and measurement of processes
- Procedure for control of non-conforming products.
- Procedure for analysis of data
- Procedure for corrective and preventive actions

- Process Approach – Quality Control
- Process Approach – Client Service

Revision History:

Revision	Significant changes	DCO #	Effective Date
00	Initial release	22-001	22/11/2022
01	The document has been updated to align as per MDR Requirements. • Precision-32 CT information has been removed	23-002	20/07/2023
02	Updated the Title of the Document	23-003	26/10/2023

Annexure – I		Glossary of Terms
Sr. No.	**Abbreviation**	
1.	Top Management	Managing Director
2.	SHPL	SEQUOIA HEALTHCARE
3.	Functional Heads	Marketing Head/Marketing General manager, Stores/Storeroom In-charge, QC In-charge, QA In-charge, Human Resource In-charge etc.
4.	GM	General Manager
5.	Ref.	Reference
6.	ANX	Annexure
7.	PRO	Procedures
8.	MR	Management Representative
9.	QMS / MD	Quality Management Systems/Medical devices
10.	NCR	Non-Conformity Report

11.	IANCR	Internal Audit Non-Conformity Report
12.	AVL	Approved Vendor List
13.	CAR	Corrective Action Report
14.	PAR	Preventive Action Report
15.	SOP	Standard Operating Procedure
16.	WD	Working Day

Annexure – III	**Roles and Responsibilities of Key Personnel**

About the Company:

Sequoia Healthcare is a privately owned business based in Bangalore with services in all over India. Sequoia Healthcare provides clients with Refurbishing, services, and Installation of Medical devices to support their client's operations and strategy. We support companies in ensuring Quality across India by providing fully trained resources who understand the regulations and can leverage this knowledge to assist our clients in their day to day operations. Sequoia Healthcare, vision is to be the premier niche provider of Medical devices Installation & services Our primary objective is to provide end to end support & solutions that enable our clients to deliver exceptional patient value.

General Manager

Education:

- Graduate in Bachelor of Commerce

Personal Traits:

- Good knowledge of different business functions
- Strong leadership qualities
- Excellent communication skills
- Highly organized
- Strong work ethic
- Good interpersonal skills
- Meticulous attention to detail
- Proactive nature

Roles & Responsibility:

- Overseeing daily business operations
- Key competence within quality oversight of medical devices
- Responsible for the Quality assurance of all device activities
- Developing and implementing growth strategies
- Training low-level employees and staff

- Creating and managing budgets
- Improving revenue
- Hiring employees
- Evaluating performance and productivity
- Analyzing accounting and financial data
- Researching and identifying growth opportunities
- Generating reports and giving presentations

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Marketing Manager

Education:

- Bachelor's in Economics

Personal Traits:

- Establish positioning, identify target audiences, and develop marketing plans with specific objectives across different channels and segments
- Lead the execution of marketing programs from start to finish, leveraging internal support and driving collaboration
- Analyze customer insights, consumer trends, market analysis, and marketing best practices to build successful strategies
- Create, maintain, and conduct analytics reporting across multiple platforms and extract key insights for future campaign development and go-to-market strategies, complete with formal proposals and recommendations on tactics
- Partner with email, performance marketing and web teams to design, test and evolve lead nurturing tactics

Roles & Responsibility:

- Working in partnership with the creative team, develop creative briefs and guide creative direction to meet objectives for all advertising and public-facing communications, including print, digital, and video assets
- Conceptualize and execute on multi-channel campaigns across the prospect and customer lifecycle, ensuring the alignment of communications and messaging across all channels

- Manage content and updates for customer and internal touch points, establishing budget guidelines, participating in events, documenting business processes, and providing additional sales support
- Gather customer and market insights to inform outreach strategies, increase customer conversions, and generate more qualified leads
- Identify effectiveness and impact of current marketing initiatives with tracking and analysis, and optimize accordingly
- Present ideas and final deliverables to internal and external teams, and communicate with senior leaders about marketing programs, strategies, and budgets

About the Company:

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Field service Engineer (Servicing & Installation)

Education:

- Bachelor of Engineering in Electrical

Personal Traits:

- Setting Up, Inspect, Operating, Repair, Performing Maintenance on and Troubleshooting
- Good Communication skills
- Time management
- Technical skills

Roles & Responsibility:

- Install medical equipment
- Follow detailed assembly Instructions, Processes, and Procedures to correctly assemble Medical Devices.
- Test & calibrate part & equipments of Medical devices
- Repair & replace parts
- Perform preventive maintenance & service
- Keep records of maintenance & repairs
- Perform manual assembly & attend training sessions
- Explain & demonstrate how to operate medical equipment
- Manage replacement of medical equipment
- Perform routine scheduled maintenance to ensure the sophisticated equipment

Annexure –IV	QUALITY OBJECTIVE

QUALITY ASSURANCE:

QUALITY OBJECTIVE	Indicator/KPI	TARGETS	TIME FRAME
Achieve a high level of customer satisfaction	No. of customer complaints	Zero customer complaints	Review at the end of year
	Customer feedback Survey results (Quality)	Average rating higher than 3.	Review at the end of year
Provide a responsive Customer service	1) Response 2) Servicing 3) Installation 4) Root Cause	95% of customer requests 1) Response: 1 Working day 2) Servicing: 4 Working days 3) Root Cause: 10 Working days	Review at the end of year
Ensure timely release of finished refurbished medical devices	1) Max completion time for verification/review 2) Max completion time for release	1) Within 2 WDs 2) Within 3 WDs	Review at the end of year

Refurbishing:

QUALITY OBJECTIVE	Indicator/KPI	TARGETS	TIME FRAME
Maintain a high level of System reliability	Maximum machine downtime during refurbishing hours	Systems downtime < 10% during working hours	Review at the end of year
Maintain the ability to recover the Systems in the event of a disaster	Maximum average recovery time	Not more than 6 hours of complete access	Review at the end of year

SUPPLY CHAIN OBJECTIVES:

QUALITY OBJECTIVE	Indicator/KPI	TARGETS	TIME FRAME
Infrastructure for storage condition monitoring	Completion of effective servicing, Installation and commissioning monitoring System.	By the end of year	During transportation & after we ship the MD, Monitoring shall be conducted on a Monthly basis. Appropriate corrective & preventive action shall be taken in any deviation.
To implement optimum stock levels	1) Determine 3-month sale forecast value 2) Build-up MD stock for supply	1) By the end of year 2) By the end of year	Every three month of refurbishing / (Quarterly)

Marketing MANAGEMENT:

QUALITY OBJECTIVE	Indicator/KPI	TARGETS	TIME FRAME
To meet the sales for demand of the SH medical devices	Two indicators: 1) Degree of fulfillment of sale target from the beginning to 31st December, 2020 2) No. of critical safety incidents	1) Minimum 95% fulfillment 2) Zero critical safety incidents	End of FY

Overall profitability of the organization.	Expenditure exceeding budgeted figures	Zero exceeding	End of FY