

Advanced Electronic Manufacturing Solutions



Quality Manual

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QUALITY MANUAL SIGNATURES

Michael J McCarthy

President

Ron McMillen

Controller

Christina M McCarthy

Secretary / Treasurer

Tom Post

Quality Assurance Manager

QUALITY POLICY

"IT IS THE POLICY OF THE COMPANY TO PRODUCE PRODUCTS OF SUCH QUALITY THAT THEY WILL RELIABLY PERFORM THEIR INTENDED FUNCTION SO THAT THE COMPANY IS RECOGNIZED AS A QUALITY LEADER IN THE INDUSTRY"

Sibex is committed to achieve its Quality Policy through the implementation and maintenance of a quality system that is relevant to internal goals and consistently meeting customer / regulatory requirements. Sibex policy objectives shall be pursued as follows:

- Strive for zero defects.
- Produce the best product at the lowest cost.
- Measure how we are doing using audits and reviews.
- Establish quality targets for product improvement.
- Provide on time deliveries.
- Do preventive actions to eliminate problems, (with emphasis on listening to the customer).
- Obtain continuous, (never ending) improvement in quality and productivity.

Qualified personnel and documented procedures will be used to control all process that affect product quality.

SCOPE:

This manual defines the requirements of Sibex Inc. in the assembly and testing of surface-mount and through-hole printed circuit boards assemblies as described in Standard Industrial Classification (SIC) 3672 and per ISO 9001 and ISO 13485 standards require.

CORPORATE PROFILE

Sibex is a very cost effective and efficient answer to customer’s electronic manufacturing needs. We provide the teamwork and attention to detail needed to produce quality products at the lowest possible cost and deliver it to the customer’s door on time.

We will answer technical questions throughout all phases of the operation. From automated assembly to quality assurance to our fully insured parts storage, you can be sure Sibex can deliver. In order for you to keep an edge on the competition we offer manufacturability studies to get your product to the market quickly and at the lowest possible cost. Developing a manufacturing process concurrent with the design is essential for achieving maximum performance in quality and product cost. We provide advice on documentation, fabrication process; testing, hardware, software, CAD and layout that will help keep costs low and quality high.

QUALITY MANUAL INTRODUCTION:

This manual describes the quality systems applicable to the products manufactured by Sibex, Inc.

The Quality Manual promotes the adoption of a process approach when developing, implementing, maintaining, and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

When used within a Quality Management System, such an approach emphasizes the importance of:

- Understanding and meeting customer and regulatory requirements.
- The need to consider processes, in terms of added value.
- Obtaining results of process performance and effectiveness, and continual improvement of processes based on objective measurements.

THE MODELS OF A PROCESS BASED QUALITY MANAGEMENT SYSTEM

Figure 1 below illustrates that customers play a significant role in defining requirements as “inputs”. Monitoring of customers satisfaction requires the evaluation of information relating to customers perception as to whether the organization has met the customer requirements as “output”.

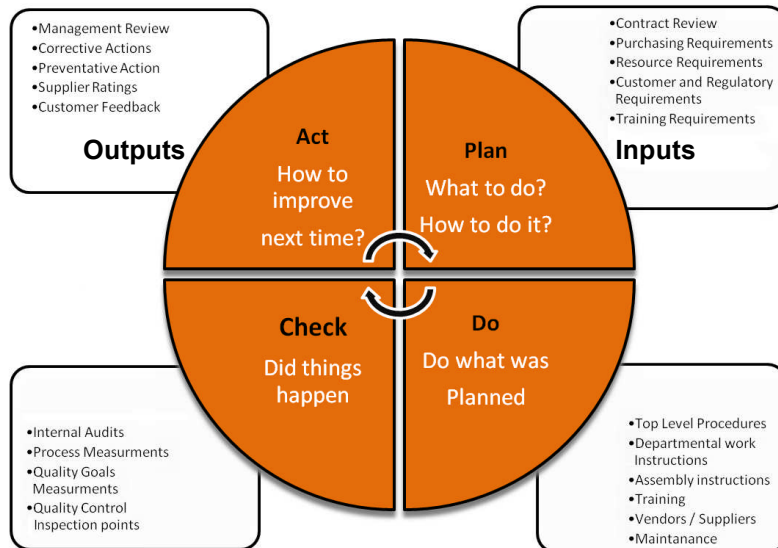


Figure 1 - ISO 9001 / ISO 13485 process models for Quality Management vs. ISO Standards.

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Table 1 – ISO 9001, ISO 13485 Sibex Inc. Quality Management vs. ISO Standards

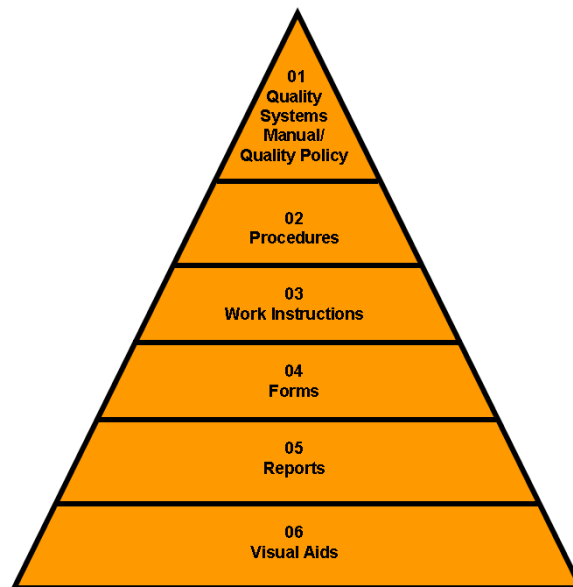


Figure 2 – The documentation structure of the Sibex Quality Management System

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4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Sibex has an established Quality System; it is documented, implemented and maintained. To show how it meets regulatory requirements and how Sibex ensures compliance through internal audits. Sibex also has a system in place to review, evaluate, and address customer satisfaction through a process of continual improvement.

4.1.1 Permissible exclusions and non-applicable requirements

The Following Sections of the ISO 9001 and ISO 13485 Standards are not applicable to Sibex,

- 7.3 Design and Development
Design and Development is completed by the customer
- 7.5.1.2.2 Installation
Installation of products produced by Sibex is completed by the customer and / or end user
- 7.5.1.2.3 Service Provision
Service provision is an OEM requirement, Sibex products are limited to warranty repair
- 7.5.2 Validation of process for production
Sibex currently has no processes which cannot be verified
- 7.5.2.2 and 7.5.1.3 Sterile Products
Sibex does not currently have any sterile product requirements
- 7.5.3.2.2 Active Implantables and Implantable devices
Sibex does not currently produce any implantable devices.

4.1.2 The processes needed for the QMS have been Identified (See Table 1).

4.1.3 The sequence and interaction of these processes has been determined. (See Figure 1)

4.1.4 Sibex has determined criteria and methods needed to ensure that both the operation and the control of these processes are effective

4.1.5 Executive management ensures the availability of resources and information necessary to support the operation and monitoring these processes, including the development of appropriate departments to handle defined responsibilities as part of the Quality Management System

4.1.6 Systems to monitor, measure, and analyze these processes have been developed

4.1.7 Implementation of actions necessary to achieve planned results, maintain the effectiveness and continual improvement of these processes.

4.1.8 Additional processes may be added to the process flow as shown (Figure 1), as new customer products and/ or regulatory requirements are introduced,

4.1.9 Sibex ensures controls over any outsourcing of processes that may have an effect on product quality See Procedure (SX -000-02-009).

4.2 General Documentation Requirements

4.2.1 General

Sibex ISO 9001 / ISO 13485 Quality Management system documentation includes:

- Documented statement of Sibex quality policy and quality objectives
- Quality Manual
- All required documented procedures, which are implemented and maintained (See Appendix A)
- Documents needed to ensure the effective planning, operation and control of processes
- Records required by the ISO 9001 / ISO 13485 Quality Management System
- Any documents specified by national or regional regulations

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For each type of medical/ military device Sibex maintains a file containing or identifying documents defining product specifications and quality system requirements. These documents define the complete manufacturing process and are retained for at least the lifetime of the product as defined by Sibex or contract, but not less than the retention period of any resulting record or as specified by relevant regulatory requirements.

- 4.2.2** The criteria and methods of operation have all been documented within the quality system with reference to information as required. These documents are reviewed for adequacy and approved prior to use; controlled, available, readily identifiable, and legible. Changes to and current revision of these documents are identified. Documents of external origin are identified and controlled. Documents are reviewed, updated and re-approved as necessary.

Changes to controlled documents are reviewed and approved by either the original approving function or another designated function with access to pertinent background information.

Obsolete documents are identified and controlled to prevent their unintended use. The retention period is defined and documented. See (SX -000-02-003)

- 4.2.3** Records have been established, are legible, and are maintained to provide evidence of conformity to the QMS. A documented procedure (SX -000-02-006) ensures the controls needed for the identification, storage, protection, retrieval, retention time and disposition of these records. These records are retained for at least the lifetime of the product as defined by Sibex or contract, but not less than two years from the date of product release by Sibex or as specified by relevant regulatory requirements.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Sibex Management communicates the importance of this Quality Management System, meeting customer, regulatory and statutory requirements to all Sibex employees. This is achieved through:

- An established Quality Policy
- Management reviews
- Ensuring availability of resources
- Employee Training
- Communicating Quality Objectives and Measurements
- New Product Readiness Meetings and reviews

5.2 Customer Focus

Sibex top executives ensure the customer and regulatory requirements are determined and are met. Sibex top executives complete this with the goal of enhancing customer satisfaction. Regular feedback from customers, contract review, and new product review ensure these requirements are met.

5.3 Quality Policy

Sibex top executives ensure that the quality policy:

- Is communicated and understood within the organization
- Includes a commitment to comply with requirements, maintain and continually improve the effectiveness of the quality management system.
- Provides a framework for establishing and reviewing quality objectives and customer satisfaction.
- Is appropriate to its objectives, and is reviewed for suitability

5.4 Planning

5.4.1 Quality Objectives

Sibex Quality Objectives have been established at relevant functions and are documented within the Quality Management System. These objectives are measurable and results are reviewed and adjusted to ensure the Sibex overall company objectives are being met and are consistent with the quality policy.

5.4.2 Quality Management System Planning

Quality Management System planning is carried out as to meet the requirements of the ISO Standard in Section: 4.1 and to define quality objectives. The Integrity of the Quality Management System MS is maintained when changes to the QMS are planned and implemented through management review and approval.

5.5 Responsibilities, Authority and Communication

5.5.1 Responsibility and Authority

All members of management are responsible for implementing, and maintaining the quality systems and procedures within their respective areas of authority. Responsibilities are defined in the organization chart. See (SX-000-06-007)

Sibex ensures that all personnel performing or verifying work have sufficient independence and authority to perform the required tasks. This authority can be found in operational procedures and other documents defining these activities

5.5.2 Management Representative

The Quality Manager is the quality representative to management and oversees the Quality Assurance Organization of the company. Quality assurance has the responsibility and authority to establish, implement, and maintain the quality system to meet the appropriate ISO requirements.

The Quality Manager is responsible for reporting on the performance of the quality system to Executive management. Executive management will use the information as a basis for improvement of the quality system.

The Quality Manager is the contact person for suppliers and customers on matters relating to the Sibex Quality System. The Quality Manager is also the liaison to the registrar.

Quality assurance has the organizational freedom to identify problems; to initiate, recommend, solve and/or verify solutions to quality problems; and to assess management at any level if action is required.

The Quality Manager will and has the responsibility to promote this awareness of customer / regulatory requirements throughout the company

5.5.3 Internal Communication

Communication between all personnel in regards to the Quality Management System is achieved through documentation of the system, training, and meetings between all personnel. The Quality Manager will also be responsible for assuring that the effectiveness of Quality Management System is understood and communicated throughout the organization.

5.6 Management Review

5.6.1 General

Sibex's executive management reviews the quality system at least once a year. The purpose of the review is to ensure the effectiveness and continuing suitability / adequacy of the quality system to meet the requirements of the ISO standard and Sibex's Quality Policy and objectives. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System. Top management is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded. See (SX-000-02-004)

5.6.2 Review Input

Inputs have been identified as part of the agenda set for the management review. At a minimum these inputs shall include:

- Follow up actions from previous management reviews
- Changes that could affect the Quality Management System
- Recommendations for improvement
- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of preventative and corrective actions
- New or revised regulatory requirements.

5.6.3 Review Outputs

The output from the management review will be recorded in the form of minutes and a list of action items. At a minimum the list of action items will show:

- Any improvements needed to maintain and improve the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Resources are provided by Sibex to ensure implementation, maintenance and continual improvement of the Quality Manual system. Resources required for addressing regulatory requirements, customer requirements, personnel, infrastructure, working environment, process equipment, materials, and information is also provided.

The determination of these resource needs is completed during management review meetings, contract reviews; new product readiness reviews, and training evaluations. Determination of these requirements is also made through customer feedback, internal audits, and monitoring / measuring activities among others.

6.2 Human Resources

6.2.1 General

All personnel at Sibex have adequate experience; training and education to ensure they can fulfill their responsibilities as it affects product quality.

6.2.2 Competence, Awareness and Training

The necessary competence of personnel performing work effecting quality of product will be determined. Sibex will provide training, and evaluate the effectiveness of the training, or the effectiveness of other actions taken, to ensure personnel performing work effecting quality of product meet the required competence. Appropriate records of specialized certifications, education, training, skills and experience are maintained. See (SX-000-02-007)

Sibex ensures its personnel are aware of the relevance, and importance, of their activities and how they contribute to the achievement of the quality objectives through training and other activities. All personnel who manage, perform, and verify work affecting quality, are responsible for implementing the quality system.

Any tasks, customer or regulatory requirement, that are identified as requiring specific skills, training, education or qualifications will be addressed and the resources will be provided for and records will be kept.

Personnel having been identified as working under special environmental conditions, proper training will be provided, and / or proper supervision will be available.

The Quality Manager has the prime responsibility for coordinating, monitoring and auditing the system. Effectiveness of the quality system will be regularly assessed by way of internal audits and management reviews.

6.3 Infrastructure

Sibex has determined the criteria for and provides the infrastructure to achieve conformity to product requirements and to ensure facilities are maintained, temperature controlled and clean. Adequate workspace, software, hardware, equipment, information systems, and transportation are available and maintained to perform all processes within the Quality Management System.

Where process equipment maintenance could affect product quality, the required maintenance activities have been documented including frequency of activity, or the lack of, and possible effects to product quality as required.

Where product supplied may contaminate other product, processes and / or procedures will be created to ensure containment is effective.

6.4 Work Environment

The work environment is air-conditioned and each person is provided with a workspace and associated equipment/furniture to be able to perform their tasks. The work environment is controlled for temperature, lighting, cleanliness, and noise conditions. Where work environment is required to be monitored and controlled, as to avoid having an adverse affect on product quality, the requirement(s) will be included in the procedure for product development.

Sibex has documented procedures for health, cleanliness and clothing of personnel, to prevent adverse affect to the quality of the product. See (SX-000-02-013). Additional requirements are specified in product work instruction and assembly procedures.

Invasive medical devices are not supplied by Sibex; therefore work environment controls required in terms of health, cleanliness and sterilization do not apply. This includes training and monitoring of these requirements. See section 4.1.1

Personnel whom may be required to temporally work in special environmental conditions are properly trained or supervised by trained personnel. (SX-000-02-017)

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

Sibex plans the product realization through, controls, approvals, monitoring and setting standards to prevent problems which may arise during order processing, manufacturing and shipping. These processes will be developed, scheduled, planned, and carried out under controlled conditions in a form suitable to Sibex method of operations.

For example:

- Work Instructions, indicating the required monitoring and measuring instructions, verification, testing, and inspection criteria
- Keeping records of conformity to show evidence that all requirements of the process and products have been met.
- Development of process control and plans for key characteristics as required by the customer.
- Product standards, representative samples and illustrations as appropriate
- Quality Objectives related to the product
- Provision of resources required

Documented requirements for risk management have been developed for military, medical and other products as required. These risk management efforts are recorded and the records maintained.

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

Sibex will determine what requirements are needed to fulfill the customer's needs during the RFQ / order processes. These requirements will include:

- Requirements for specified intended use but not stated by the customer, where known
- Requirements specified by the customer for delivery and post delivery activities
- Statutory, Regulatory and legal requirements as identified.
- Customer specific requirements such as component traceability and workmanship standards.
- Material and manufacturing process requirements.
- Any additional requirements determined by Sibex.

7.2.2 Review of requirements related to product

Sibex will review said requirements needed to fulfill the customer's needs during the Contract Review process (SX-000-02-012) prior to commitment of order to customer. Records of this review shall be maintained and any actions required will be kept. To ensure that our customers get what they requested on time, traceable, and to the quality they expect from Sibex, procedures will provide that:

- Customer's requirements are unambiguous, clearly defined and documented.
- Sibex can meet customer requirements.
- Changes to customer requirements are resolved, documented and communicable to all persons affected by the changes.
- The customer will be contacted to resolve any discrepancy found during the review period, and to define any requirements which are not documented
- Any amendment to the contract will be represented by documents approved by both the customer and Sibex.

7.2.3 Customer Communication

Customer contact is the main responsibility of Program Management. Communication between Sibex and its customer is to ensure that product information including any enquiries, updates, amendments; additions, order handling etc. are handled effectively. This will also include any customer complaints, feedback, and disseminating advisory notices as required.

The customer communication procedure (SX -000-02-010) includes requirements for issuance and implementation of advisory notices

7.3 Design and Development -

Product design and development is completed at the OEM level, refer to exclusion section 4.1.1

7.4 Purchasing

7.4.1 Purchasing Process

Sibex has documented the purchasing procedure (SX -000-02-009) to ensure that purchased product conforms to specified purchasing requirements. To ensure that Sibex receives purchased product to our specified and implied needs, suppliers are evaluated, selected, and re-evaluated. Records of these evaluations, any actions required from these evaluations, and a list of approved suppliers will be maintained. This list will include franchised, non-franchised, and valued added sub-contractors. The list will be prepared on results contained from one or more of the following sources:

- Corrective Action Requests
- Questionnaires
- Audits
- Pricing
- On-time deliveries
- Non-conforming material
- Customer requirements

The type and extent of control to be exercised over suppliers may be based on:

- Type of product
- Impact on final product quality
- Results of previous quality audits
- Previously demonstrated quality capability
- Effect of the purchased product on subsequent product realization
- Customer specifications

7.4.2 Purchasing Information

Requirements for purchased product will be reviewed for adequacy prior to communication to the supplier. All purchase documentation used will clearly describe the material/service ordered including the following where applicable:

- Requirements for approval of product such as quantities, conditions, traceability, part numbers, Procedures, processes, equipment, type or other precise identification
- Inspection requirements which will be reported on certification of conformity where required, also any standards codes
- Any quality system standards to be applied to the product/services.
- Any requirements to notify Sibex of any anomalies, changes in definition or approval for the process being used.
- Additional traceability requirements as specified by contract.
- Requirements for qualification of personnel as required

Traceability records are maintained to the extent required by customer and / or regulatory requirements.

7.4.3 Verification of Purchased Products

All products received at Sibex will be verified in accordance with inspection procedures and may include:

- Records to support the quality of the product from the supplier (i.e.: C of C, Test Reports, SPC charts etc).
- Records to ensure product purchased meets specified purchasing requirements.
- Inspection of the product upon receipt.
- Records of verification will be maintained per records procedure dictates.

If verification is to be completed at the supplier's premises this information will be included on the purchasing documentation.

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7.5 Production and Service Provision

The Service / Installation section of the ISO standard is not applicable to Sibex see section 4.1.1.

7.5.1 Control of Production

Production at Sibex is completed under controlled conditions to ensure the following requirements are met:

- Information describing product characteristics is available for the product realization process.
- Procedures, product requirements, reference materials and measurement procedures have been documented for all processes where required.
- Suitable, maintained, equipment is used in all areas of production
- Monitoring and measuring devices are controlled and available to required areas of production
- Monitoring and measuring of product characteristics is defined and implemented
- Sibex has implemented requirements defining the release, delivery, and post delivery activities through monitor and measurement, shipping instructions and customer feedback procedures.

Labeling and packaging requirements are defined in documented work instructions and have been controlled, implemented, and maintained. Additional customer requirements for labeling and packaging will be defined in build instructions for specific products.

Each batch (Kit) of medical devices and / or military devices has a record of traceability that is maintained describing the amount manufactured and the amount approved for distribution. This batch record is verified and approved prior to the finalizing of the record.

Documented work instructions are available for removal of manufacturing process agents for medical / military devices as required.

7.5.2 Validation of Processes for Production

Sibex will validate any processes that the output cannot be verified by monitoring and / or measuring. There are currently no processes performed at Sibex which cannot be verified. See section 4.1.1

At such time that specific processes are identified at Sibex requiring validation, Sibex will demonstrate the ability of these processes to meet planned results.

Sibex will ensure that the following is completed:

- Defining the criteria for review and approval of such processes
- Approval of equipment and qualification of personnel
- Use of defined specific methods and procedures
- Records will be maintained and re-evaluation schedules will be determined.

Computer software validation is performed by the customer for use by Sibex to ensure product has meet requirements. This validation should be performed by the customer prior to use and re-validated performed as determined by the customer.

Sibex does not currently produce any sterile devices. See section 4.1.1

7.5.3 Identification and Traceability

Sibex will identify parts and materials for use in the manufacture of products during all phases of product realization. All purchased materials used in the manufacture of products will be traceable back to this source of supply as required by the customer.

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Assembly traceability and product realization status in regards to monitoring and measuring, is completed through the use of documented procedure (SX -000-02-018). This procedure also ensures the unique identification of the product is controlled and recorded, and that only product that has passed the required inspection and tests is released.

A documented procedure is established to ensure products returned will be identified upon receipt and segregated from production units. These will have an identification (RMA) number associated with them prior to receiving. This procedure is documented and maintained. See (SX -000-02-015).

Sibex does not currently produce any active implantable or implantable devices See Section 4.1.1.

7.5.4 Customer Property

All customer-supplied material (consignment material) shall be identified, verified, protected, and safeguarded, from unauthorized use or disposition. Consignment material may include test fixtures, tooling, drawings, electronic files, parts, raw materials, intellectual property and confidential health information. Sibex documented procedures (SX-000-02-016) shall be established so that consignment material shall be examined, upon receipt for:

- Damage
- Quantity
- Conformity

Any discrepancy shall be reported to the customer who supplied the materials and records maintained.

Proper precautions will be taken and inspection performed to assure that no damage or deterioration occurs during storage.

7.5.5 Preservation of Product

Through documented procedures Sibex shall maintain product integrity of all production materials during internal processing and delivery. See (SX-000-02-013)

For example:

Identification

- Examples of product, packaging and master carton marking as required or needed.
- Serial numbers
- Expiration date, controlling limited shelf life materials
- Regulatory marking requirements
- Traceability

Handling

- Protect the product using appropriate containers, pallets or work platforms.
- Train operators in awareness of product protection.
- Operate lift trucks, trucks, loaders, and other vehicles in a safe manner to minimize damages.
- Any goods, which are kept for extended periods of time, will be checked for shelf life damage as required.

Packaging

- Sibex will develop packaging, which provides appropriate protection during shipping, or utilize customer-supplied instructions when provided.

Storage

- Sibex provide adequate space and facilities
- Ensure cleanliness
- Maintain appropriate temperature and humidity as necessary to prevent premature degradation.
- Provide for appropriate identification marking and traceability

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Protection

- Control the temperature and humidity where required
- Segregate material to ensure identification where necessary

Delivery

- Provide for proper protection after release, per contract
- Sibex will deliver products on- time, protected and safe

Documented procedures / work instructions are implemented and maintained for the control of limited shelf life materials and for materials requiring special storage / handling as required. These storage conditions shall be controlled and records maintained.

7.6 Control of Monitoring and Measurement Equipment

Monitoring and measuring activities appropriate to demonstrate product conformity of predetermined requirements, including the equipment required for completing this, shall be documented in build work instructions and / or subsequent customer specified inspection instructions. These activities are reviewed and approved prior to use.

All measuring test equipment which could affect the quality of the finished parts will be calibrated by an external sub-contractor or in-house, in accordance with Sibex procedures (SX -000-02-001). Records of these calibrations will be maintained.

Sibex will also ensure that:

- Calibration of equipment is performed prior to use and at regular intervals. The basis for the calibration is traceable to a national standard. The basis for calibration where no such standard exists will be recorded.
- Adjustments to equipment will be made as required, and records of these adjustments maintained.
- Equipment requiring calibration is adequately identified as to the calibration status.
- Sibex equipment will be handled, cleaned, maintained and stored properly. The equipment will be safeguarded from adjustments invalidating the calibration or measurement results.

If equipment is found out of calibration, the previous calibration records will be assessed and any possible required actions regarding the equipment and effects on product requirements will be determined, acted upon and recorded.

Monitoring and measuring software used for final product verification will be confirmed prior to use and re-confirmed at specific intervals as required by customer.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Sibex continually monitors, measures, analyzes, maintains, and improves processes to demonstrate conformity to product requirements and maintain effectiveness of the quality management system. Product conformity is measured and analyzed through the use of one or more of the following:

- Inspection points
- Testing techniques
- Statistical techniques
- Process control procedures.
- Inspection sampling plans

Quality Management System monitoring and measuring includes:

- Customer satisfaction
- Quality Management System (Internal Audit)
- Process
- Product
- Continual improvement
- Corrective Action
- Preventive Action
- Control of non-conformities

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Sibex will review customer satisfaction to ensure that customer requirements have been met. This information is incorporated into the management reviews, corrective / preventative action system. Methods of obtaining and using customer satisfaction and/or dissatisfaction information may include the following:

- Customer complaints
- Customer returns
- Questionnaires and surveys
- Direct customer communication
- Customer visits
- 1st article responses
- Previous audits
- Corrective actions

A documented procedure (SX -000-02-010) has been established and is maintained for customer feedback. This ensures that Sibex has a method of early warnings to input into preventative, corrective action processes.

If National or Regional Regulations are identified that requires Sibex to gain experience from the post production phase it will be included in the feedback system.

8.2.2 Internal Audit

Internal audits will be used with the goal of continual improvement of Sibex's Quality Management System. These ensure the Quality Management System conforms to planned arrangements, that it is implemented and maintained. The audit schedules, criteria, scope, and methods are defined. See (SX -000-02-011) Sibex's audit program includes:

- Audits will be carried out against documented procedures and regulatory requirements on a yearly schedule
- The schedule will be set based on importance of area to be audited
- Follow-up corrective action and results of these audits will be documented and reported
- All auditors have been trained and will be selected independent of the area to be audited.
- Records will be maintained of the audit and reviewed during the next audit scheduled for effectiveness.
- Corrective actions noted during previous audits will be verified for effectiveness.
- Managers and / or supervisors of the department being audited ensure that required actions from audit results are completed without undue delay. These actions should eliminate the non-conformities and there causes.

8.2.3 Monitoring and Measurement of Processes

All quality system processes at Sibex will be monitored, and where applicable, measured. These measurements are to demonstrate the ability of the process to achieve planned results. This will be achieved through the internal audit program and the inspection process. In addition, continuous improvement practices will be realized during the internal audit process.

Correction and corrective actions shall be taken when planned results are not achieved.

8.2.4 Monitoring and measurement of Product

To ensure product requirements have been met, Sibex will monitor and measure product characteristics at appropriate stages during the product realization process; this is completed using documented procedures.

Sibex inspection and test procedures are in operation to ensure that product conforms to specification requirements. These may include:

- Incoming materials
Procedures for inspection and verification
- In-process product
Procedures for identifying and inspecting products
- Finished product
Procedures that ensure that inspection and tests are completed
Shippable product conforms to requirements

The identity of personnel performing inspection and test activities will be recorded and maintained. Product will not be released until all planned arrangements have been met. Evidence of conformity to product requirements and the person authorizing release of said product is recorded and maintained.

8.3 Control of Nonconforming Product

Non-conforming material will be identified, controlled, documented, evaluated and prevented, from unintentional usage or shipping. Responsibility for disposition of non-conforming product is defined, and when required, the customer is contacted. Procedures are established and maintained that prevent the inadvertent use of non-conforming material or product. See [\(SX-000-02-005\)](#)

Sibex policy is to identify, document, and prevent re-occurrence of all non-conformances. Non-conforming reports give indication where and when corrective action is required.

Non-conforming material is defined as any material or component, or assembly, which does not conform to product specifications, engineering drawings, or associated quality standards. Any material or assembly that is suspected of being non-conforming shall be considered non-conforming until proven otherwise.

Non-conforming material must be identified and segregated, (so as to prevent non-conforming material product from being used or shipped), by means of non-conforming material form, product identification tags, or on the spot rework.

In all cases, non-conforming product is re-inspected and re-verified in accordance with written procedures.

All reworked material requiring a non-conforming report (rework which restores the functional capability of a non-conforming article in a manner that precludes compliance of the article with applicable drawings or specifications) will be reviewed by a Material Review Board (MRB) consisting of: Quality Manager, Production Manager, Process Engineering or their pre-designated representative(s), and one or more of them shall provide disposition.

The disposition decision may include:

- Return to supplier
- Rework or repair
- Accept as is
- Scrap
- Re-grade for an alternate application

Non-conforming material may be used when dictated by contract. The customer representative will be contacted to gain approval and allowance for the non-conformity. This approval can only occur if all regulatory requirements have been met. The person(s) authorizing this concession is maintained.

When non-conforming product is detected after delivery, the potential effects will be reviewed and appropriate action will be taken.

Rework process shall be documented in a work instruction which has undergone the same approval process as the original work instruction. Prior to authorization and approval of the work instruction, a determination of adverse effects of the rework shall be made and documented.

8.4 Analysis of Data

Sibex has a documented system (SX-000-02-014) to collect and analyze data from our Quality Management System. This analysis evaluates the effectiveness of the Quality Management System to determine if improvements can be made. This data may include:

- Results of internal audits
- Trends of processes and product including opportunities for preventative action
- Process control and process capability studies
- Determination of quality levels in sampling plans
- Data analysis, performance assessment, and non-conformity analysis
- Process improvement
- Conformance to product requirements
- Customer Feedback
- Supplier performance

Records of this analysis will be maintained

8.5 Improvement

8.5.1 Continual Improvement

Sibex has a documented system in place, which uses a planned approach to maintaining processes, solving problems, and implementing continuous improvements. See (SX -000-02-002).

This data may include:

- Result of internal / external audits
- Corrective / preventative actions
- Management review
- Analysis of data
- Quality policy
- Quality Objectives
- Customer Complaints / surveys

Sibex will utilize this data to make improvements and to maintain to the quality systems. Continuous improvement is one of the agenda items at management review.

Implementation and issuance of advisory notices is handled per Sibex RMA procedure (SX -000-02-015) and (SX -000-02-010). If national or regional regulation requires notification, this is handled through the Program Management work instruction.

Customer complaints are recorded within the customer communication procedure. If a customer complaint is not followed up by a corrective action, the reasoning and person's authorization will be recorded. If the complaint is determined to be the result of a component manufacturer or sub-contractor the corrective action shall be obtained from them through Purchasing, Program Management and / or Quality Assurance functions.

8.5.2 Corrective Action

Sibex has a documented procedure, for reviewing, determining cause, evaluating and taking corrective action, to eliminate causes of non-conformance and prevent re-occurrence. See (SX -000-02-008).

Corrective actions shall be appropriate to the effects of the non-conformity. Determination of the corrective action is made, recorded and controls incorporated ensure that the corrective action taken is implemented.

Follow-up on the effectiveness of actions taken will be completed and documented upon full root cause analysis and implementation of the corrective action. The Quality Assurance function has the main responsibility for the verification unless stated otherwise in the corrective action request.

8.5.3 Preventive Action

Sibex will identify areas of potential improvements evaluate the need, determine and implement actions to be taken to prevent non-conformance. Potential improvements may be identified during internal audits, management reviews and continuous process improvement/preventive action process(s). Preventative actions taken shall be appropriate to the effects of the potential non-conformity. See (SX -000-02-002)

Records of preventative action investigations, implementations and review of effectiveness will be recorded.

APPENDIX A

Quality Management System Procedures

NUMBER	TITLE
SX -000-02-001	Calibration
SX -000-02-002	Continuous Improvement/Preventative Action
SX -000-02-003	Documentation
SX -000-02-004	Management Review
SX -000-02-005	Control of Non-Conforming Product
SX -000-02-006	Control of Records
SX -000-02-007	Training
SX -000-02-008	Corrective Action
SX -000-02-009	Purchasing
SX -000-02-010	Customer Communication
SX -000-02-011	Internal Audits
SX -000-02-012	Contract Review
SX -000-02-013	Materials Preservation Storage and Delivery
SX -000-02-014	Statistical techniques
SX -000-02-015	Returned Material Authorization
SX -000-02-016	Customer Supplied Material
SX -000-02-017	Radiation Protection Program
SX -000-02-018	Product Identification and Traceability

APPENDIX B:

SIBEX INC Facilities, Scope of Business and Certifications list:

Corporate and Manufacturing Division

Safety Harbor
1040 Harbor Lake Drive
Safety Harbor, FL 34695
727-726-4343
727-726-4434 (Fax)

Manufacturing Division

Largo
12722 62nd Street, Suite 204
Largo, FL 33773
727-726-4343
727-530-4336 (Fax)

Manufacturing Division

Homosassa
1760 S. Dimensions Terrace
Homosassa, FL 34448
352-795-0101

Manufacturing Division

Crystal River
430 N Suncoast Blvd 34429
352-795-0101
352-564-0772 (Fax)
ISO 9001 / ISO13485