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Advanced Electronic Manufacturing Solutions



Quality Manual ISO 9001:2000

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QUALITY MANUAL SIGNATURES

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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, customer needs and expectations. 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 with 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.



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 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 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.

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THE MODELS OF A PROCESS BASED QUALITY MANAGEMENT SYSTEM

Figures 1 and 2 illustrate the process linkages presently in clauses 4 to 8 of the ISO 9001:2000 standard. Table 3 shows the ISO 9001:2000 process models for Quality Management vs. ISO Standards.

The illustration shows 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”.

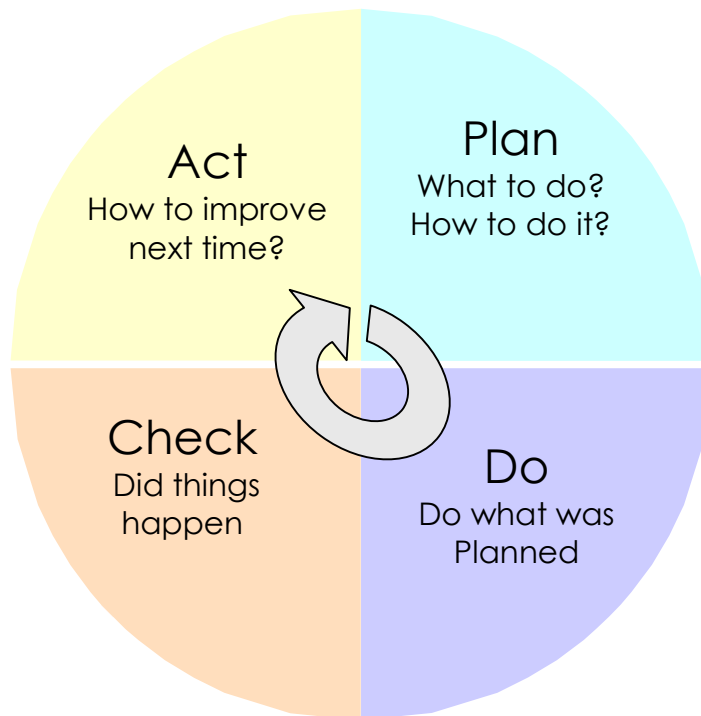


Figure 1- The “Plan-Do-Check-Act” cycle

In addition, the methodology known as “Plan–Do–Check–Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

- Plan:** Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.
- Do:** Implement the process.
- Check:** Monitor and measure process and product against policies, objectives, and requirements for the product and report the result.
- Act:** Take actions to continually improve process performance.

Continual improvement of the quality Management system

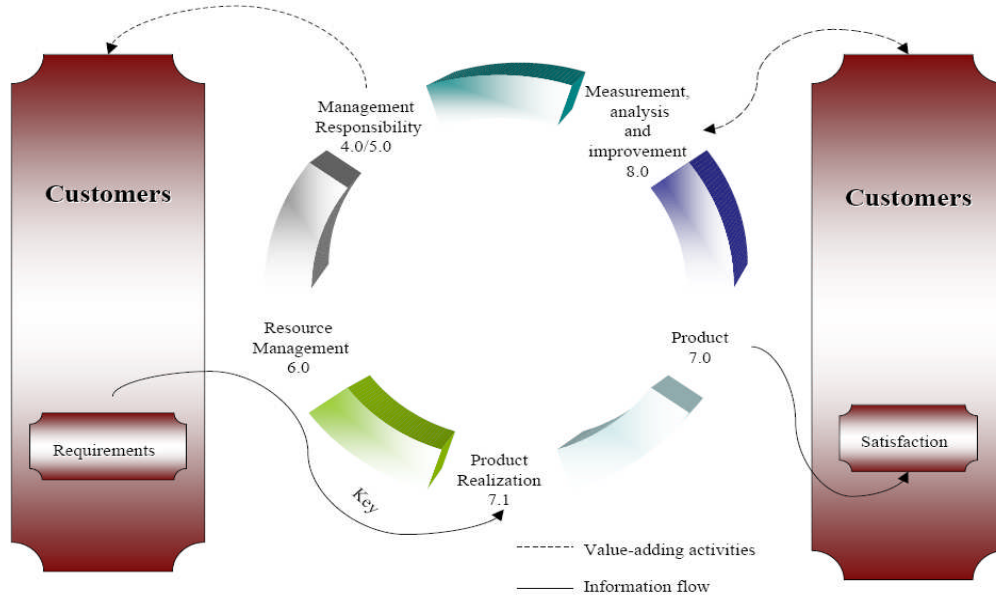


Figure 2 – Model of a process-based quality management system

4 Quality Management System	5.5 Responsibility Authority and Communication	7 Product Realization	8 Measurement Analysis and Improvement
4.1, 4.2 General Documentation Requirements	5.6 Management Review	7.1 Planning of Product Realization	8.1 General
5 Management Responsibility	6 Resource Management	7.2 Customer-Related Processes	8.2 Monitoring and Measurement
5.1 Management Commitment	6.1 Provisions of Recourses	7.3 Design and Development	8.3 Control of Nonconforming Product
5.2 Customer Focus	6.2 Human Resources	7.4 Purchasing	8.4 Analysis of Data
5.3 Quality Policy	6.3 Infrastructure	7.5 Production and Service Provision	8.5 Improvement
5.4 Planning	6.4 Work Environment	7.6 Control of Monitoring and Measuring Devices	

Table 3 – ISO 9001-2000 Process Model for Quality Management vs. Standards

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4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

To define how our Quality System is documented, implemented, meets regulatory requirements, and performs internal audits to ensure compliance. Sibex also has a system in place to review, evaluate, and address customer satisfaction through a process of continual improvement and prevent non-conformities.

4.1.1 Permissible Exclusions

The Following Section of the ISO 9001: 2000 Standard are not applicable to Sibex, Clauses 7.3 Design and Development and 7.5.1 Service Provision.

4.2 General Documentation Requirements

4.2.1 General

All procedures and documents needed to meet the ISO 9001: 2000 Standard have been identified within this Quality Manual.

4.2.2 Quality System Procedures, See (Appendix A)

4.2.3 Sibex Executive Management reviews the Quality System at least once a year. The purpose of the review is to ensure the effectiveness and continuing suitability of the Quality System to meet the requirement of the ISO 9001: 2000 standard and Sibex's Quality Policy/Objectives. The president is responsible for scheduling and conducting the reviews. Conclusions of these reviews are recorded.

4.2.4 The criteria and methods of operation have all been documented within the quality system with reference to information as required. All our processes are measured, monitored, analyzed and continually improved. Records have been established and are maintained to provide evidence of conformity to the QMS.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Sibex Management has communicated the importance of this Quality System, meeting customer, regulatory and legal requirements, and will continue to do so to all Sibex employees. This is achieved through:

- Conducting Management Reviews
- Employee Training
- Communicating Quality Objectives and Measurements

5.2 Customer Focus

Sibex Top Executives shall ensure the customer requirements are determined and are met with the goal of enhancing customer satisfaction.

5.3 Quality Policy

Sibex Top Executives shall ensure that the policy:

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

5.4 Planning

5.4.1 Quality Objectives

Sibex Quality Objectives have been identified and are documented within the Quality Management Review. These objectives are measurable and results will be reviewed and adjusted to ensure the Sibex overall company objectives are being met.

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 QMS is maintained when changes 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 ORGANIZATIONAL CHART)

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 of establishing, implementing, and maintaining a quality system that meets the appropriate ISO 9001 requirements.

The QA 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 QA 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 awareness of the customer requirements will be reviewed during contract review, management quality meetings, design meetings and/or continuous improvement meetings.

5.5.3 Internal Communication

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

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 of the quality system to meet the requirements of the ISO 9001:2000 standard and Sibex's Quality Policy and objectives. The President is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded.

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5.6.2 Review Input

Inputs have been identified as part of the agenda set for the Management Review. These inputs include all of the requirements of the standard and others as required.

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. The list of action items will show:

- Any areas of system process improvements
- Resource needs
- Any change to Quality objectives and policy
- Customer material return reports
- Results of Internal, External, Customer, Government audits
- Records/minutes/actions from management meetings
- Improvement of Product related to customer requirements

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Resources will be provided by Sibex to ensure that all processes are implemented and any customer concerns are dealt within a timely manner. Reference 8.2.1 Customer Satisfaction, indicates methods used to ensure customer satisfaction to meet customer requirements.

6.2 Human Resources

6.2.1 General

All personnel at Sibex will be trained, educated, and have adequate experience to ensure they fulfill their responsibilities.

6.2.2 Competence, Awareness and Training

All personnel who manage, perform, and verify work affecting quality, are responsible for implementing the quality system.

Any tasks that are identified as requiring specific skills; training, education or qualifications will be provided for, and records will be kept. Re-Certifications will be completed annually.

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

6.3 Infrastructure

Sibex Facilities are maintained, temperature controlled and clean. There is adequate workspace, software, hardware, and equipment to perform all processes within the quality system. This includes control of the inspection and calibration areas.

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.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

To plan, control, approve, monitor and set standards to prevent problems which may arise during order processing, manufacturing and shipping. These processes will be scheduled, planned and carried out under controlled conditions. For example:

- Work Instructions, and acceptance/rejection criteria
- Keeping records to support conformity of the process.
- Development of process control and plans for key characteristics as required by the customer.
- Product standards, representative samples and illustrations as appropriate

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:

- Delivery times
- Engineering and test support
- Statutory, Regulatory and legal requirements are identified.
- Customer specific requirements such as component traceability and workmanship standards.
- Material and manufacturing process requirements.

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 processes. 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.
- 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 any updates, amendments, additions, etc. are handled effectively. This will also include any customer complaints, feedback, and/or product requirements.

Where applicable information derived from previous similar designs will be utilized when not in conflict with non-disclosure agreements.

7.3 Design and Development - NOT APPLICABLE

Sibex does not plan and control the design and development of any products. This is our Customer's responsibility. Sibex is a Electronic Manufacturing Company.

7.4 Purchasing

7.4.1 Purchasing Process

To ensure that Sibex receives supplied product to our specified and implied needs, a list of approved suppliers will be maintained. This list will be prepared on results contained from one or more of the following sources:

- CAR's
- Questionnaires
- Audits

The extent of control to be exercised over suppliers will be based on:

- Type of product
- Impact on final product quality
- Results of previous quality audits
- Previously demonstrated quality capability

7.4.2 Purchasing Information

All purchase documentation used will clearly describe the material/service ordered including the following where applicable:

- Quantities, conditions, traceability, part numbers, type or other precise identification
- Inspection requirements which will be reported on certification of conformity where required, also any standards codes
- Any quality systems standard 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.

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).
- Inspection of the product upon receipt.

If verification of the parts is to take place at Sibex facilities, or if Sibex chooses to verify the parts at the supplier's facilities, then this will be on the contract with the vendor.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

The Service section of the ISO 9001: 2000 standard is not applicable to Sibex. Sibex does not carry out production and service provision. This is our customer's responsibility.

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

- Technical data is available to verify the parts being manufactured/supplied.
- Procedures/Work Instructions have been documented for all processes where required.
- Measuring instruments are used as required to verify the product.
- Monitoring of receiving, inspection, packaging and shipping processes.
- All jobs are processed and completed using approved documentation, generated from and following the intent of customer supplied information.

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7.5.2 Validation of Processes for Production and Service Provision

Any specific processes identified at Sibex will be qualified prior to use and their process parameters defined. For example:

- Ensure that all equipment requirements are identified, and that equipment and facilities meet those requirements.
- Identify all process factors (potential variables) that may affect the capability of the product or service to meet customer product quality requirements.
- Evidence that material specifications are compliant.
- Record of periodic re-validation.

7.5.3 Identification and Traceability

Sibex will identify all parts and materials used in the manufacture of products during all stages of receipt, manufacture, inspection, packaging, and shipping for traceability and inspection status, (pass, fail or on hold). All materials used in the manufacture of products purchased will be traceable back to this source of supply if required by the customer.

7.5.4 Customer Property

All customer-supplied material (CSM) shall be identified and protected from unauthorized use or disposition. CSM will include tooling, drawings, electronic files, parts and raw materials. Sibex documented procedures shall be established so that CSM shall be examined, upon receipt for:

- Damage
- Quantity
- Completeness and the correct material or characteristic
- Any discrepancy shall be reported to the customer who supplied the materials.
- Proper precautions will be taken and inspection performed to assure that no damage or deterioration occurs during storage.

7.5.5 Preservation of Product

Sibex shall prevent materials from being damaged and control inventory for efficient cycle time of stock materials. For example:

Identification

- Examples of product, packaging and master carton marking as required or needed.
- Serial numbers
- Expiration date
- 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

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

7.6 Control of Monitoring and Measurement Devices

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. Sibex will also ensure that:

- Basis for calibration is traceable to a national standard.
- Inspection and test equipment affecting quality will be listed.
- Records of calibration will be maintained with positive recall provisions.
- Procedures will explain what to do with previous results when equipment is found out of calibration.
- Sibex calibration will be conducted in a suitable environment when necessary, temperature, cleanliness etc.
- Sibex equipment will be handled, cleaned, maintained and stored properly.
- Adjustments to equipment will be recorded.
- Inspection measuring and test equipment shall also include any personal tools, used for final verification.
- Software that operates test equipment will be controlled and maintained in Document Control.
- Computer hardware / software will be calibrated in accordance with Sibex procedures if used as final measuring device.

8.0 MEASUREMENT ANALYSIS AND IMPROVEMENT

8.1 General

All material will be inspected as it is received, and processed prior to shipping to ensure conformity to the product and purchase order specifications. Statistical techniques to identify and monitor these activities will be used.

Inspection documentation shall be maintained as evidence of product and process conformance. These may include:

- Any unique inspection equipment used
- Any sub-contracted inspection activities
- Acceptance and rejection criteria, or reference to them
- The sequence of operations shall show when inspection took place.

Sibex will monitor and measure:

- Customer Satisfaction
- Quality Management System (Internal Audit)
- Process
- Product
- Continual Improvement

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- Corrective Action
- Preventive Action
- Control of non-conformities

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Sibex will review customer satisfaction as part of the management reviews and corrective action system to implement continuous improvements. 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
- Trade association information
- Industry group information
- Previous audits
- Corrective action noted during audits

8.2.2 Internal Audit

The effectiveness of our quality system will be verified. Methods used to measure this may include:

- Audits will be carried out against procedures 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.
- Corrective actions noted during previous audits will be verified

8.2.3 Monitoring and Measurement of Processes

All processes at Sibex will be monitored to ensure that they are suitable to ensure the customer requirements are being met. 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.

8.2.4 Monitoring and measurement production

All material received, processed, stored, packaged and shipped from SIBEX will be inspected to procedures and records of the results will be kept.

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

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8.3 Control of Nonconforming Product

Non-conforming material will be identified, documented, evaluated and prevented, from being used or shipped. Responsibility for disposition of non-conforming product will be defined, and when required, the customer is contacted. Procedures are established and maintained that prevent the inadvertent use of non-conforming material or product.

Sibex policy is to identify and document all non-conformances that do not conform to the applicable standard, regardless of how easily they can be reworked or repaired. The non-conformity reports are an invaluable tool in tracking performance and trends that give indication where and when a 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 or tag or on the spot rework, which will be documented.

In all cases, repaired or reworked products are re-inspected in accordance with written procedures, and a Material Review Board (MRB) consisting of: QA Manager, Production Manager and Process Engineering or their pre-designated representative(s), shall provide disposition on all non-conforming material. 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 or the customer's purchasing representative will be contacted to gain approval and allowance for the non-conformity.

8.4 Analysis of Data

Sibex has a documented system to collect and analyze data from our quality management system. This data includes:

- Results of internal audits
- Corrective action log
- Process control and process capability studies
- Determination of quality levels in sampling plans
- Data analysis, performance assessment, and non-conformity analysis
- Process improvement
- Safety evaluation and risk analysis
- Reference 8.2.1 Customer Satisfaction for continuous improvements.

8.5 Improvement

8.5.1 Continual Improvement

Sibex has a documented system in place, which uses a planned approach to solving and implementing continuous improvements. This data may include:

- Result of internal audits
- Corrective action log
- Management review
- Analysis of data
- Quality policy

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

8.5.2 Corrective Action

Sibex has a documented system for taking corrective action to eliminate causes of non-conformance.

Corrective actions ensure the effective handling of customer complaints and product non-conformities. They may aid in identifying the causes of non-conformities relating to product process(s). They also insure the quality systems are investigated, and the results are recorded. Determination of the corrective action is made and controls incorporated insure that the corrective action taken is implemented.

Follow-up on the effectiveness of actions taken will be completed as part of the next internal audit.

An action will be taken when appropriate to prevent the recurrence of the problem.

8.5.3 Preventive Action

Sibex will identify areas of potential improvements and actions to be taken to prevent non-conformance. This will be done as part of our Internal Audit, Management Reviews and Continuous Process Improvement/Preventive Action process(s).

APPENDIX A

Quality System Procedures

NUMBER	TITLE
SX -000-02-001	Measurement and Test Equipment (Calibration)
SX -000-02-002	Continuous Improvement/Preventative Action
SX -000-02-003	Document Control
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	Suppliers
SX -000-02-010	Customer Complaints
SX -000-02-011	Internal Audits
SX -000-02-012	Contract Review
SX -000-02-013	Packaging and Delivery
SX -000-02-014	Statistical techniques
SX -000-02-015	RMA
SX -000-02-016	Customer Supplied Materials.
SX -000-02-017	Radiation Protection Program