



ABRAXSIS TECHNOLOGIES

Baltimore - New York

QUALITY SYSTEM MANUAL

ISO 9001:2008

AS 9120:2002

REVISION A

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QUALITY SYSTEM MANUAL

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SCOPE STATEMENT

Abraxis Technologies is a privately held woman owned independent distributor of component level electronics located in a Hub-Zone. Our headquarters is a 22k sq. ft. warehouse in Hunt Valley, Maryland and our Sales Office is located in Ronkonkoma, New York. Our company is the collaboration of a group of management professionals with 75 years of combined experience in the electronics industry.

Abraxis Technologies combines technical solutions, high volume logistical resources, and value added services to meet the needs of its suppliers and customers. We create demand for suppliers, solutions for customers and opportunity for our employees.

Our Quality Management System (QMS) has been developed to meet the requirements of ISO 9001 and AS 9120 Quality Management Systems Requirements. Our Inspection System is in accordance with IDEA Std-1010A, and our ESD controls are in accordance with ANSI ESD S20.20. The QMS does not include Design and Development activities, since Abraxis Distributor Sales does not design or develop products.

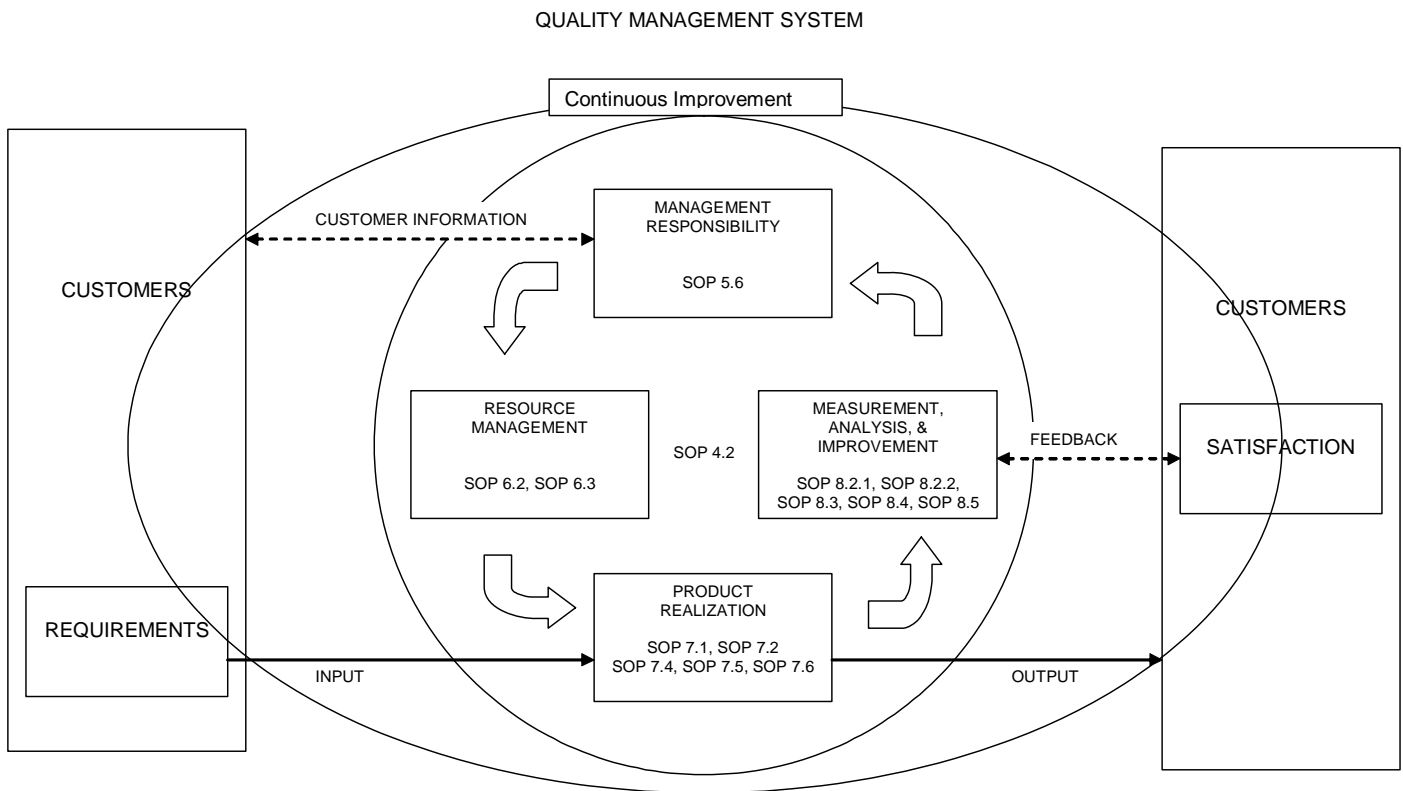
Our Mission is that we will...

- Be the preferred strategic link between our suppliers and customers.
- Reduce the cost of acquisition to our customers.
- Guarantee a quality product

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4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

Executive Management has established and maintains a documented Quality Management System, which meets the requirements of ISO 9001 and AS 9120. The Quality Management System is continually improved for effectiveness in accordance with these Standards.

Management has:

- a) determined the processes needed for the Quality Management System and their application throughout the organization,
- b) determined the sequence and interaction of these processes,
- c) determined criteria and methods needed to ensure that both the operation and the control of these processes are effective,
- d) ensured the availability of resources and information necessary to support the operation and monitoring these processes,
- e) monitored, measured (where applicable), and analyzed these processes, and
- f) implemented actions necessary to achieve planned results and continual improvement of these processes.

Where Management chooses to outsource any process that affects product conformity to requirements, Management will ensure control over these processes. The type and extent of control to be applied to these outsourced processes is defined within the Quality Management System.

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These processes are managed in accordance with Standards Operating Procedure (SOPs) developed to meet the requirements of the Standards.

4.2 Documentation Requirements

4.2.1 General

The Quality Management System is documented and includes a Quality Policy and quality objectives, a Quality Manual, documented procedures and records required by the Standards (ref. sect. 4.2.4 Control of Records), documents, including records determined to be necessary to ensure the effective planning, operation, and control of processes, and quality system requirements imposed by any regulatory authorities.

Personnel have access to and are made aware of relevant Quality Management System documentation and changes.

4.2.2 Quality Manual

The Quality Manual includes:

- the scope of the Quality Management System, including details of and justification for any exclusions,
- the documented procedures established for the Quality Management System, or references to them, including clearly showing the relationship between the Standards and the documented procedure, and



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- a description of the interaction between the processes of the Quality Management System.

4.2.3 Control of Documents

Documents required by the Quality Management System are controlled. Records are controlled in accordance with section 4.2.4.

Executive Management has established and maintains a documented procedure to define the controls needed:

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin determined to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.



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Appropriate documentation will be maintained to verify the status of the product, including manufacturer's data, Standards, etc. Document changes will be coordinated with Customer and/or Regulatory Authority contract or regulatory requirements.

Document control will be performed in accordance with SOP 1-2, Documentation.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the Quality Management System are controlled.

Executive Management has established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records.

Records will be maintained so as to remain legible, readily identifiable, and retrievable.

Records will include, when applicable, manufacturer and distributor test and inspection reports, original certificates of conformity, nonconformance and corrective action records, lot traceability records, and environmental and shelf life condition records.



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Where records are stored in an electronic form, the integrity of the system and the back-up procedures will be validated. These records without possibility of change by software, will be traceable to the original documentation.

Records of product origin, conformity, and shipment are maintained for a minimum of seven years, or as required by contract. Records will be made available for review by Customers and Regulatory Authorities in accordance with contract or regulatory requirements.

Records are controlled in accordance with SOP 1-2, Documentation.

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5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Executive Management has demonstrated a commitment to the development and implementation of the Quality Management System, and continually improving its effectiveness by:

- communicating to the Company the importance of meeting Customer as well as statutory and regulatory requirements,
- establishing the Quality Policy
- ensuring that Quality Objectives are established,
- conducting management reviews, and
- ensuring the availability of resources.

Management commitment is addressed in SOP 2-6 Management Responsibility.

5.2 Customer Focus

Executive Management will ensure that Customer requirements are determined and fulfilled with the aim of enhancing Customer Satisfaction.

Customer focus is addressed in SOP 2-6 Management Responsibility.

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5.3 Quality Policy

Executive Management will ensure the Quality Policy is appropriate to the purpose of the Company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the Quality Management System. The Quality Policy will provide a framework for establishing and reviewing Quality Objectives. Executive Management will ensure that the Quality Policy is communicated and understood within the Company, and is reviewed for continuing stability.

The Company Quality Policy is:

“Abraxis Technologies is committed to satisfying our Customers through the maintenance and continuous improvement of our Quality Management System.”

The Quality Policy is addressed in SOP 2-6 Management Responsibility.

5.4 Planning

5.4.1 Quality Objectives

Executive Management has established Quality Objectives at relevant functions and levels within the Company. These Quality Objectives are measurable and consistent with the Quality Policy.

The Quality Objectives are addressed in SOP 2-6 Management Responsibility.

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5.4.2 Quality Management System Planning

Executive Management will ensure that the planning of the Quality Management System is carried out in accordance with the Standards, as well as the Quality Policy. Executive Management will also ensure that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

Quality Management System planning is performed in accordance with SOP 4-1, Planning

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Executive Management has defined and documented the responsibility, authority, and the interrelation of personnel who manage, perform, and verify work within the Quality Management System. Executive Management has developed an organization chart that depicts the quality organization, and is addressed in SOP 2-6 Management Responsibility.

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5.5.2 Management Representative

Executive Management has appointed a Management Representative for the Quality Management System. The Management Representative has the responsibility and authority that includes:

- ensuring that processes needed for the Quality Management System are established, implemented, and maintained,
- reporting on the performance of the Quality Management System to Executive Management and any need for improvement,
- ensuring the promotion of awareness of Customer requirements throughout the Company, and
- the organizational freedom and direct access to management to resolve quality matters.

Appointment of the Management Representative is addressed in SOP 2-6 Management Responsibility.

5.5.3 Internal Communication

Executive Management has established appropriate communication processes within the Company and ensures that communication takes place regarding the effectiveness of the Quality Management System.

Responsibility, authority, and communication is addressed in SOP 2-6 Management Responsibility.

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5.6 Management Review

5.6.1 General

Executive Management will conduct a review of the Quality System on a periodic basis to ensure its continued suitability and effectiveness in accordance with the Quality Policy and Objectives. This review will include assessing opportunities for improvement and the need for changes to the Quality Management System, including the quality policy and quality objectives.

5.6.2 Review Input

The input to management review includes:

- results of audits,
- Customer feedback,
- process performance and product conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- planned changes that could affect the Quality Management System,
and
- recommendations for improvement.



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5.6.3 Review Output

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

- improvement of the effectiveness of the Quality Management System and its processes,
- improvement of product related to Customer requirements, and
- resource needs.

Management review is performed in accordance with SOP2-6 Management Responsibility.

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6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Executive Management has determined and provided the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness, and to enhance Customer Satisfaction by meeting Customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements will be competent on the basis of appropriate education, training, skills, and experience.

6.2.2 Competence, Training and Awareness

Executive Management:

- determines the necessary competence for personnel performing work affecting conformity to product requirements,
- when applicable, provides training or take other actions to achieve the necessary competence,
- ensures that the necessary competence has been achieved,

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- ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives, and
- maintains appropriate records of education, training, skills, and experience (ref. sect. 4.2.4 Control of Records)

Human resources is addressed in SOP 3-2, Training.

6.3 Infrastructure

Executive Management has provided and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes:

- building, workspace, and associated utilities,
- process equipment, both hardware and software, and
- supporting services (such as transport, communication, or information systems).

Infrastructure is addressed in SOP 3-3, Infrastructure and Work Environment.

6.4 Work Environment

Executive Management manages the work environment needed to achieve conformity to product requirements.

Work environment is addressed in SOP 3-3, Infrastructure and Work Environment.

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7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

Executive Management plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the Quality Management System.

In planning product realization, Executive Management determines the following, as appropriate:

- Quality Objectives and requirements for the product,
- the need to establish processes and documents, and to provide resources specific to the product,
- required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance,
- records needed to provide evidence that the realization processes and resulting product fulfill requirements (ref. sect. 4.2.4 Control of Quality Records).

The output from this planning is in a form suitable for the Company's method of operations.

Planning of product realization is performed in accordance with SOP 4-1, Planning.

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7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Executive Management will determine:

- requirements specified by the Customer, including the requirements for delivery, and for post-delivery activities,
- requirements not stated by the Customer but necessary for specified use or known and intended use,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements as considered necessary by the Company.

7.2.2 Review of Requirements Related to the Product

Executive Management will review the requirements related to the product. This review will be conducted prior to the Company's commitment to supply a product to the Customer and will ensure that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved,
- the Company has the ability to meet the defined requirements, and
- risks (e.g., new technology, short delivery time scale) have been evaluated.

Records of the results of the review and actions arising from the review will be maintained (ref. sect. 4.2.4 Control of Quality Records).

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Where the Customer provides no documented statement of requirement, the Customer requirements will be confirmed by the Company before acceptance. Where product requirements are changed, the Company will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Executive Management has implemented effective arrangements for communicating with Customers in relation to:

- product information,
- inquiries, contracts, or order handling, including amendments, and
- customer feedback, including customer complaints.

Customer related processes are addressed in SOP 4-2 Order Entry and Customer Communication.

7.3 **Design and Development**

Abraxis Technologies does not design or develop products.

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7.4 Purchasing

7.4.1 Purchasing Process

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

Executive Management evaluates and selects suppliers based on their ability to supply product in accordance with the Company's requirements. Criteria for select, evaluation, and re-evaluations established. Records of the results of evaluations and any necessary actions arising from the evaluation will be maintained (ref. sect. 4.2.4 Control of Quality Records).

Executive Management maintains a listing of Approved Suppliers that includes the scope of the approval, periodically reviews supplier performance, and uses these records to establish the level of controls to be implemented.

Abraxis Technologies will:

- maintain a listing of Approved Suppliers that includes the scope of their approval,
- periodically review supplier performance, using records of the reviews as a basis for establishing level of controls to be implemented,
- define the necessary actions to take when dealing with suppliers that do not meet requirements,



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- prevent the purchase of counterfeit/suspect unapproved products.

Abraxis Technologies assumes responsibility for the quality of all products purchased from suppliers, including Customer-designated sources.

7.4.2 Purchasing Information

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

- requirements for approval of product, procedures, processes, and equipment,
- requirements for qualification of personnel, and
- quality management system requirements
- the name or other positive identification, and applicable issues of specifications, drawing, process requirements, inspection instructions and other relevant technical data,
- requirements relative to supplier notification to Abraxis Technologies of nonconforming product,
- requirements for the supplier to notify Abraxis Technologies of changes in product and/or process definition,
- right of access by Abraxis Technologies, Customers, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- requirements for a certificate of conformity, test reports, and/or airworthiness approval from the approved manufacturer or approved repair station (when required).

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Executive Management ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

Executive Management has established and implemented inspection and other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include:

- obtaining objective evidence of the quality of the product from suppliers and verifying the authenticity of the accompanying documentation (e.g., certification of conformity from the manufacturer, test reports, statistical records, process control),
- review of required documentation, and
- inspection of products upon receipt.

Where the Company or the Customer intends to perform verification at the supplier's premises, the intended verification arrangements and method of product release will be stated in the purchasing information.

Where specified in the contract, the Customer or the Customer's Representative will be afforded the right to verify at the supplier's premises and Abraxis Technologies' premises that subcontracted product conform to specified requirements.

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Verification by the Customer will not be used as evidence of effective control of quality by the supplier and will not absolve Abraxis Technologies of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the Customer.

Purchasing is performed in accordance with SOP 4-4 Purchasing.

7.5 Product and Service Provision

7.5.1 Control of Production and Service Provision

Product and service provision is planned and carried out under controlled conditions. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product,
- the availability of work instructions,
- the use of suitable equipment,
- the availability and use of monitoring and measuring equipment,
- the implementation of monitoring and measurement, and
- the implementation of product release, delivery, and post-delivery activities.

7.5.2 Validation of Processes for Product and Service Provision

Processes for production and service provision are validated where the resulting output cannot be verified by subsequent monitoring or measurement and as a

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consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of the processes to achieve planned results.

Executive Management has established arrangements for these processes including, as applicable:

- defined criteria for review and approval of the process,
- approval of equipment and qualification of personnel, use of specific methods and procedures,
- requirements for records (ref. sect. 4.2.4 Control of Quality Records), and
- revalidation.

7.5.3 Identification and Traceability

Where applicable, the product will be identified by suitable means throughout product realization. Product status will be identified with respect to monitoring and measurement requirements throughout product realization.

Acceptance authority media are used (e.g., stamps, electronic signatures, passwords) under documented controls for the media.

Where traceability is a requirement, the unique identification of the product will be controlled and records maintained (ref. sect. 4.2.4 Control of Quality Records).



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Procedures have been established for product identification and traceability from receipt, during splitting, storage, packaging, and preservation operations, and until delivery (including subcontracted handling or packing operations).

Processes provide for:

- maintaining the manufacturer's identification and batch/lot traceability,
- the ability to identify and trace products manufactured from the same batch of raw material or from the same manufacturing batch, as well as the ability to trace the product to the ultimate destination (delivery, scrap),
- maintaining the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Identification and Traceability is addressed in SOP 4-5 Product and Service Provision.

7.5.4 Customer Property

Care will be exercised with Customer property while it is under the Company's control or being used by the Company. Customer property for use or incorporation into the product will be identified, verified, protected, and safeguarded. If any Customer property is lost, damaged, or otherwise found to be unsuitable for use, Abraxis Technologies will report this to the Customer and maintain records (ref. sect. 4.2.4 Control of Quality Records).

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7.5.5 Preservation of Product

Products will be preserved during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

Preservation of product will also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- a) cleaning,
- b) prevention, detection and removal of foreign objects,
- c) special handling for sensitive products,
- d) marking and labeling including safety warnings,
- e) shelf life control and stock rotation,
- f) special handling for hazardous materials,
- g) environmental controls(e.g., temperature, humidity).

The System ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

Product and service provision is performed in accordance with SOP 4-5 Product and Service Provision.



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7.6 Control of Monitoring and Measuring Equipment

Executive Management has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

A register of the monitoring and measuring equipment is maintained, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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

Calibrations are performed under environmental conditions that are suitable for the calibrations, inspections, measurements and tests being carried out.

Measuring equipment is calibrated or verified, or both, at specific intervals, or prior to use, against measurement Standards traceable to the National Institute of Standards and Technology (NIST). Where no such Standards exist, the basis used for calibration or verification is recorded (ref. sect. 4.2.4).

Measuring equipment will be adjusted or re-adjusted as necessary, have identification in order to determine its calibration status, safeguarded from adjustments that would invalidate the measurement result, protected from



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damage and deterioration during handling, maintenance, and storage, and recalled to a defined method when requiring calibration.

Previous measuring results are assessed and the validity recorded when the equipment is found not to conform to requirements. Appropriate action will be taken on the equipment and any product affected.

Records of the results of calibration and verification are maintained (ref. sect. 4.2.4 Control of Quality Records).

When used in the monitoring and measurement of specific requirements, the ability of computer software to satisfy the intended application is confirmed. This is done prior to initial use and reconfirmed as necessary.

Control of monitoring and measuring devices is performed in accordance with SOP 4-6 Control of Monitoring and Measuring Equipment.

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8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General

Executive Management plans and implements the monitoring, measurement, analysis, and improvement of processes needed to demonstrate conformity to product requirements, ensure conformity of the Quality Management System, and continually improve the effectiveness of the Quality Management System.

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

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the Quality Management System, information relating to Customer perception is monitored to determine whether the Customer requirements have been fulfilled. Executive Management has developed a method for obtaining and using this information.

8.2.2 Internal Audit

Internal audits are conducted at planned intervals to determine whether the Quality Management System conforms to the planned arrangements, the requirements of the Standards, and the Quality Management System

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requirements established by the Company, and are effectively implemented and maintained.

An audit program has been planned, taking into consideration the status of and the importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods have been defined. The selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records, and reporting results.

Records of the audit and its results are maintained (ref. sect. 4.2.4 Control of Quality Records).

The management responsible for the area being audited ensures that any necessary corrections or corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (ref. sect. 8.5.2 Corrective Action).

Internal audits will also meet contract and/or regulatory requirements.

Internal Audits are performed in accordance with SOP 5-2.1 Internal Audits.

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8.2.3 Monitoring and Measurement of Processes

Methods have been applied for monitoring, and where applicable, measurement of the Quality Management System. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate.

In the event of process nonconformity, the following will occur:

- a) appropriate action is taken to correct the nonconforming process,
- b) evaluation is made to determine whether the process nonconformity has resulted in product nonconformity, and
- c) identification and control the nonconforming product in accordance with section 8.3.

8.2.4 Monitoring and Measurement of Product

The characteristics of the product is monitored and measured to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with acceptance criteria is maintained.

Records indicate the person(s) authorizing release of product for delivery to the customer (ref. Sect. 4.2.4).

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When inspections are performed to verify product status and sampling inspection is used as a means of verification, the plan will be statistically valid and appropriate for use. The plan will preclude the acceptance of lots whose samples have known nonconformities. When required, the plan will be submitted for Customer approval.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product (ref. sect. 4.2.4 Control of Quality Records).

The release of product and delivery of service to the customer does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by Executive Management, and where applicable, by the Customer.

8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance will be documented, and will include:

- a) criteria for acceptance and/or rejection,
- b) a record of the measurement results, and
- c) type of measurement instruments required and any specific instructions associated with their use.

Test records will show actual test results data when required by specification or acceptance test plan.

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8.2.5 Evidence of Conformance – Certificate of Conformity

When required, the Customer will be provided evidence of the product's conformity to its technical specifications. This may include the manufacturer's conformance documents, the original airworthiness certificate, test analysis, and/or test reports. When splitting product, copies of original documents will be annotated with the following information: amount delivered relative to amount received, purchase order number, customer's name, and supplier's name.

Where there is a formal agreement with the Customer, a Certificate of Conformity that references the original manufacturer's conformance documents that are retained and traceable, will be provided.

Monitoring and measurement is performed in accordance with SOP 5-2.2, Inspection and Testing.

8.3 Control of Nonconforming Product

Product that does not conform to product requirements are identified and controlled to prevent its unintended use or delivery. Executive Management has established a documented procedure to define the controls and related responsibilities and authorities for dealing with nonconforming product.



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A documented procedure defines the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

Where applicable, nonconforming product is dealt with in one or more of the following ways:

- by taking action to eliminate the detected nonconformity,
- by authorizing its use, release, or acceptance under concession by Executive Management and, where applicable, by the Customer,
- by taking action to preclude its original intended use or application.
- by taking action appropriate to the effects or potential effects of the nonconformity when nonconforming product is detected after delivery or use has started.

Dispositions are limited to:

- scrap
- return to supplier
- rejection for revalidation by the manufacturer (if applicable)
- submittal to design activity or Customer for "use-as-is" disposition, when required by contract
- rework (where not restricted by contract)

Products dispositioned for scrap will be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.



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Provisions will be made, with the manufacturer where necessary, to ensure that similar supplies are not similarly affected, and will inform the Customer of any nonconformities affected product already delivered.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (ref. sect. 4.2.4 Control of Quality Records).

When nonconforming product is corrected it is subjected to re-verification to demonstrate conformity to the requirements.

In addition to any contract or regulatory authority reporting requirements, the System will provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification will include a clear description of the nonconformity, which includes as necessary parts affected, Customer and/or internal part numbers, quantity, and date(s) delivered.

Control of nonconforming product is performed in accordance with SOP 5-3, Control of Nonconforming Product.

8.4 Analysis of Data

Executive Management collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the Quality Management System, and to evaluate where continual improvement of the effectiveness of the Quality

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Management System can be made. This includes data generated as a result of monitoring and measurement, and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction (ref. sect. 8.2.1),
- conformity to product requirements (ref. sect. 8.2.4)
- characteristics and trends of processes and products, including opportunities for preventive action (ref. sect. 8.2.3 and 8.2.4), and
- suppliers (ref. sect. 7.4).

Analysis of data is performed in accordance with SOP 5-4, Analysis of Data.

8.5 Improvement

8.5.1 Continual Improvement

Executive Management continually improves the effectiveness of the Quality Management System through the use of the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.2 Corrective Action

Action is taken to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions will be appropriate to the effects of the nonconformities encountered.

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Executive Management has established a documented procedure to define the requirements for:

- reviewing nonconformities, including Customer complaints,
- determining the causes of nonconformities,
- evaluating the need for action to ensure nonconformities do not recur,
- determining and implementing action needed,
- records of the results of action taken (ref. sect. 4.2.4 Control of Quality Records),
- reviewing the effectiveness of corrective action taken,
- flow down of the corrective action requirement to a supplier and/or manufacturer, when it is determined that the supplier and/or manufacturer is responsible for the root cause, and
- specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive Action

Action is taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action will be appropriate to the effects of the potential problems.

Executive Management has established a documented procedure to define the requirements for:

- Determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,



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- determining and implementing action needed,
- records of the results of action taken (ref. sect. 4.2.4 Control of Quality Records),
- reviewing the effectiveness of preventive action taken, and
- the withdrawal of product(s) from stock that are suspected of a noncompliance (or returned by a Customer), including notification of all Customers of the action(s) taken who have purchased the product from the same lot or batch.

Improvement is performed in accordance with SOP 5-5, Improvement.