

ADVANCED MEASUREMENT  
LABS, INC.

Quality System Manual

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APPROVALS

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2/11/04

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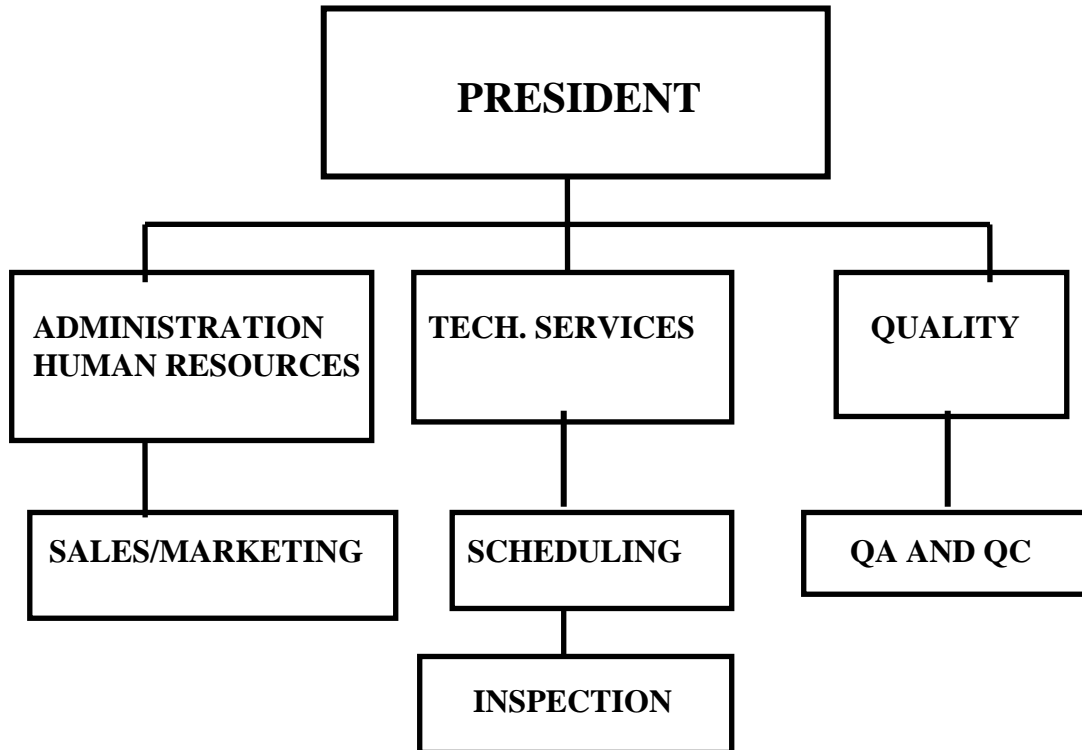
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## ORGANIZATION CHART



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## **Introduction**

Advanced Measurement Labs, Inc. a service company. Its only business is to inspect parts to customer specifications, consult and advise customers on technical issues. Advanced Measurement Labs, Inc. does not assemble or manufacture in part or whole any product. The purpose of this manual is to describe the Quality Assurance Program implemented by Advanced Measurement Labs, Inc. (hereafter referred to as AML) AML is currently in compliance to ISO9001:2000 and Customer requirements. The policy of AML will be to apply this Quality Assurance Program to all Phases of our operation. Written procedures and work instructions for implementation of the Quality Assurance Program will be established as dictated by the service performed and the level of instructions needed.

The Quality Assurance Manager / President shall review the Quality Assurance Manual Annually for compliance to the requirements of ISO9001:2000 in the latest revision, and make the necessary changes in the Quality Assurance Manual.

### **1 SCOPE**

#### **1.1 General:**

The Quality Program will assure that the specifications of ISO 9001 and customer requirements will be applied to all contracts. This International Standard specifies requirements for a quality management system where an organization:

- a) Needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

#### **1.2 Application.**

The Quality Program is applicable when

- A) the service specifications are stated in terms of an established Industry specification, Manufacturer's specification from the customer or,
- B) when service is specified for interim of unique demands where no Specification exists , but criteria for acceptance is established.

### **2 NORMATIVE REFERENCE**

The following normative document contains provisions, which, through reference in this text, constitute provisions of ISO 9000:2000 Quality management system-

Fundamentals and vocabulary. Documents related to this policy document include:

all procedures referenced within the pages of this document.

all work instructions that directly or indirectly have impact on inspection activities.

all forms used in conjunction with in this policy and the procedures and work instructions described in both of the above.

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**3 TERMS AND DEFINITIONS**

For the purposes of this International Standard, the terms and definitions given ISO 9000 apply.

**4 QUALITY MANAGEMENT SYSTEM**

**4.1 General requirements**

This quality management system has been created, is being maintained, is implemented and will be continually improved to achieve compliance with ISO 9001:2000 and customer requirements. AML shall:

- a) AML will identify the process needed for the quality management and their applications throughout AML.
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyze these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

Quality system requirements imposed by the applicable regulatory authorities. The criteria and methods for control of processes are found in internal procedures, inspection instructions and work instructions. The information necessary for the operation and monitoring of these processes is found within available controlled documents. Upon the completion of measurement and monitoring of the processes, appropriate action is taken to assured intentions are achieved and opportunities for improvement are acted on. AML does not outsource any inspection service to a supplier.

**4.2 Documentation requirements**

**4.2.1 General**

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by ISO 9001:2000 and customer requirements.,
- d) documents needed by AML to ensure the effective planning, operation and control of its processes and
- e) records required by ISO 9001:2000 and customer requirements. (see 4.2.4).
- f) quality system requirements imposed by the applicable regulatory authorities.

AML shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

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Where the term “documented procedure” appears within ISO 9001:2000 and customer requirements., this means that the procedure is established, documented, implemented and maintained.

**4.2.2 Quality Manual**

AML quality manual shall be maintained and reviewed yearly for its continued acceptability by the Director Quality Assurance or the President. The Quality Manual shall include;

- a) The scope of the Quality Management system, including details of and justifications for any exclusion if applicable.
- b) The documented procedures established for the quality management system, or reference to them by an index listing the procedures. When referencing the documented procedures, the relationship between the requirements of ISO 9001 or customer specifications, the documented procedure shall be clearly shown.
- c) A description of the interaction between the processes of the quality management system by means of flow charts, procedures, or work instructions.

**4.2.3 Control of Document**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
- h) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use. Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

AML shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

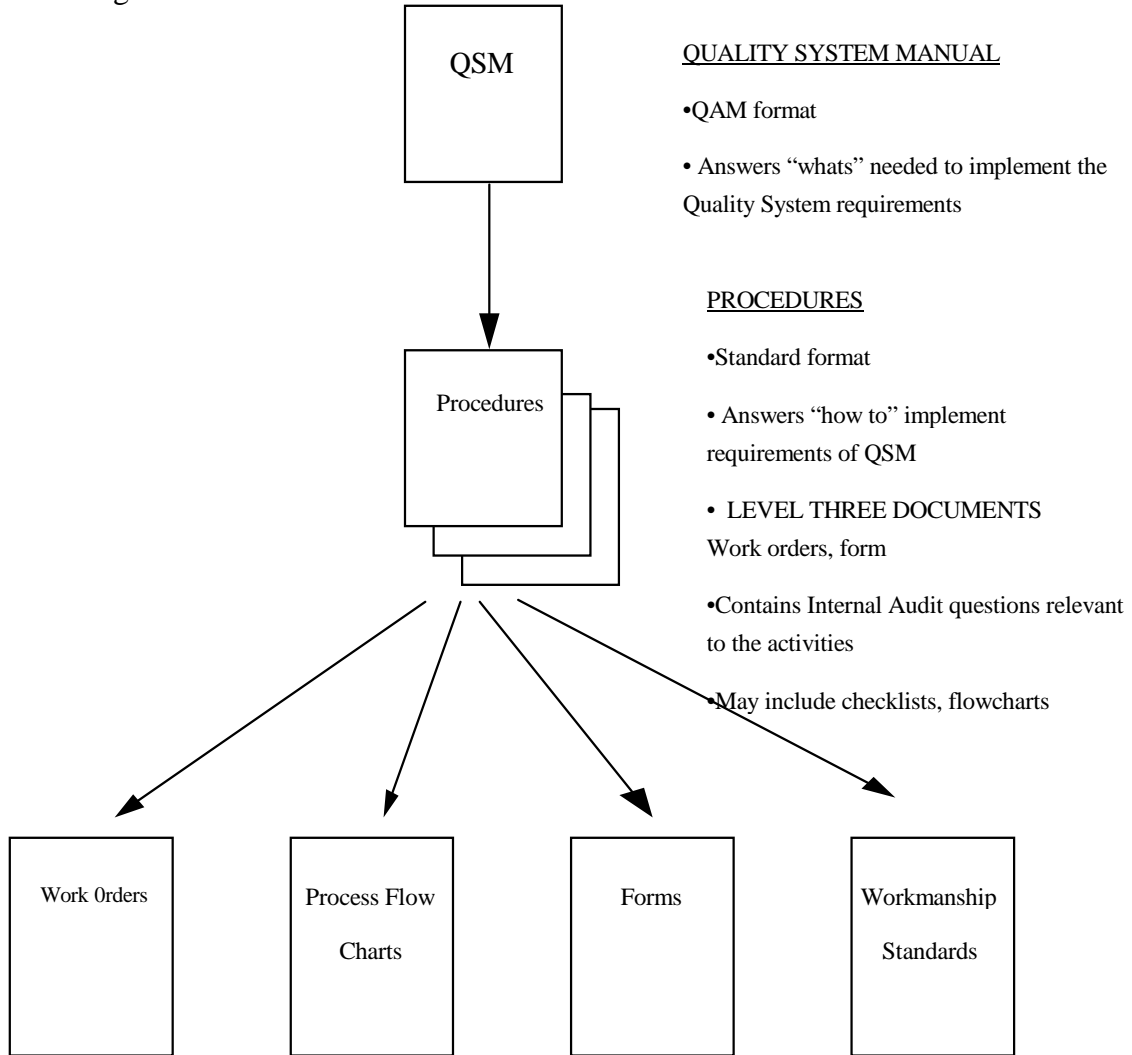
Where practical, the nature of the change will be identified in the document or the appropriate attachments.

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**4.2.3.1 Documentation Structure**

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Internally generated documentation which implement all Quality System requirements will be structured into three levels of documents as noted in the following:



**4.2.4 Control of Records**

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

All quality records will be legible and will be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records will

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be established and recorded. Where agreed contractually, quality records will be made available for evaluation by the customer or the customer's representative and regulatory agencies.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Note: Records may be in the form of any type of media, such as hard copy or electronic media. Records retained for ISO9001:2000 and listed below are the minimum required. Logs, tags, reports, checklists, forms, etc. are completed and maintained to provide objective evidence of product (inspection) realization.

**4.3 Configuration Management**

AML shall establish, document and maintain a configuration management process appropriate to the product being inspected. The following are elements that will be controlled as required by the complexity and appropriateness of the product being inspected. *Configuration Identification*: This is the process of defining and identifying every element of the product being inspected. *Configuration Control*: this is a series of actions, which manages a design change from the time of the original proposal for change through implementation of approved changes. *Configuration Accounting*; This is the process of recording the status of proposed changes and the implementation status of approved changes. When customer changes are submitted, they will be incorporated and controlled after agreement by AML and the customer as to implementation date.

**5 MANAGEMENT RESPONSIBILITY**

**5.1 Management commitment**

The President shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources

**5.2 Customer Focus**

The President ensure that customer requirements are determined by review of customer contracts and are met by monitoring customer quality data in regards to acceptance, rejections, and corrective actions, and delivery of service on-time by means of monitoring delivery to P.O. requirement.

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**5.3 Quality Policy**

The President shall ensure that the quality policy

- a) is appropriate to the purpose of AML
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within AML, and
- e) is reviewed for continuing suitability.

**Company Quality Policy**

AML shall strive to deliver the service and value that meet or exceed the customer's requirements.

AML shall commit to comply with all applicable requirements and to constant improvement by training its people, upgrading equipment and eliminating nonessential practices.

AML will monitor, measure and analyze its processes for continuous improvement of its Management System throughout the year. Management will review all monitoring data during its Management Review for continuing suitability and effectiveness of the Quality Management System.

This Quality Policy is carried out and implemented at all levels in the organization. All AML training will begin with review of Quality Policy.

**5.4 Planning**

**5.4.1 Quality objectives**

The President shall ensure that quality objectives, including those needed to meet requirements for the processing of product being inspected (see 7.1 a)], are established at relevant functions and levels within AML. The quality objectives shall measurable and consistent with the quality policy.

**5.4.2 Quality Management System Planning**

The President shall ensure that:

- a) the planning of the quality management system relevant to meet the requirements given in 4.1, by means of work instructions, procedures, and documented training, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented..

**5.5 Responsibility, Authority, and Communication**

**5.5.1 Responsibility and authority**

Top management shall ensure that responsibilities and authorities are defined and communicated within AML.

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**5.5.2 Management Representative**

The President has appointed the Director Quality Assurance as “Management Representative” with the responsibility and authority for:

- a) ensuring that processes needed for the quality management system are established, implemented, and maintained.
- b) reporting on the performance of the quality management system to the highest level of management reporting on the need for improvement of the quality management system to the highest level of management overseeing the implementation and maintenance of the quality system in accordance with ISO 9001:2000 and customer requirements.
- c) ensuring the promotion of awareness of customer requirements throughout AML
- d) The organizational freedom to resolve matters pertaining to quality.

**5.5.3 Internal communication**

Director Quality Assurance shall ensure that appropriate communication processes are established within AML and that communication takes place regarding the effectiveness of the quality management system.

**5.6 Management Review**

**5.6.1 General**

The President shall review AML’s quality management system yearly to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).

**5.6.2 Review Input**

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product being inspected conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement,

**5.6.3 Review Output**

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of the inspection process related to customer requirements, and
- c) resource needs.

Management review records are maintained.

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**6 RESOURCE MANAGEMENT**

**6.1 Provision of Resources**

AML shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction meeting customer requirements.

**6.2 Human Resources**

**6.2.1 General**

Anyone at AML having an assignment associated with any of the processes of the quality management system must be competent through education, skills, training and/or experience as necessary. Requirements for education, skills, training and experience can be found in the job descriptions.

**6.2.2 Competence, Awareness and Training**

AML shall:

- a) determine the necessary competence for personnel performing work affecting inspection and documentation quality,
- b) provide training or take other actions to satisfy these needs,
- c) evaluate the effectiveness of the actions taken,
- d) ensure 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
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

**6.3 Infrastructure**

The President (with input and assistance from his staff) determines, provides, and maintains the infrastructure needed to achieve conformity to product being inspected requirements. Infrastructure includes, as applicable:

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport or communication).

**6.4 Work environment**

AML shall determine and manage the work environment needed to achieve conformity to product being inspected requirements.

NOTE Factors that may affect the conformity of the product being inspected include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

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**7 PRODUCT REALIZATION**

**7.1 Planning of Product Realization**

AML shall plan and develop the processes needed for product being inspected realization. Planning of product being inspected realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product being inspected realization, AML shall determine the following, as appropriate:

- a) quality objectives and requirements for the product being inspected;
- b) the need to establish processes, documents, and provide resources specific to the product being inspected;
- c) required verification, validation, monitoring, inspection and test activities specific to the product being inspected and the criteria for product being inspected acceptance;
- c) records needed to provide evidence that the realization processes and resulting product being inspected meet requirements (see 4.2.4).
- e) the identification of resources to support operation and maintenance of the product being inspected.

The output of this planning shall be in a form of a work order or quality plan.

**7.2 Customer-related processes**

**7.2.1 Determination of Requirements Related to the Product**

AML shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for the specified or intended use, where known,
- c) statutory and regulatory requirements related to the product being inspected, and
- d) any additional requirements determined by AML.

**7.2.2 Review of Requirements Related to the Product being inspected**

AML will review the requirements related to the product being inspected. This review shall be conducted prior to AML's commitment to inspect a customer product, or orders, acceptance of changes to contracts or orders) shall ensure that

- a) product being inspected requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) AML has the ability to meet the defined requirements.
- d) risk (e.g., new technology, short delivery time scale) have been evaluated.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer

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requirements shall be confirmed by AML before acceptance.

Where product being inspected requirements are changed, AML shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Note In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product being inspected information such as catalogues or advertising material

**7.2.2.1 Contract Review**

AML's "Contract Review Procedure", defines the requirements for contract review and for the coordination of all related activities.

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order will be reviewed by AML to ensure that:

The requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, AML will ensure that the order requirements are agreed before their acceptance.

Any differences between the contract or order requirements and those in the tender are resolved.

AML has the capability to meet the contract or order requirements.

Quality planning is an integral part of the contract review process.

Customer requirements that modify the engineering definitions are controlled and implemented.

**7.2.2.2 Amendment to a Contract**

AML will identify how an amendment to a contract is made and correctly transferred to the functions concerned within AML's organization.

Management will determine the required dates, configuration, quantity, and other customer requirements. If AML cannot meet the requirements, the President will notify the customer and other arrangements or concessions will be made and documented.

**7.2.2.3 Records**

Records of contract reviews will be maintained (see 4.2.4).

Records of requirements reviews and follow-on actions are maintained as Quality Records.

**7.2.3 Customer Communication**

AML shall determine and implement effective arrangements for communicating with customers in relation to

- a) product being inspected information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

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documented on the Supplier Procedure for continuation on the AML approved supplier list.

#### **7.4.2 Purchasing Information**

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

- a. requirements for approval of product, procedures, processes and equipment,
- b. requirements for qualification of personnel, and
- c. quality management system requirements
- d. the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- e. requirements for design, test, examination, inspection and related instructions for acceptance by AML,
- f. requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g. requirements relative to
  - supplier notification to AML of nonconforming product and
  - arrangements for AML approval of supplier nonconforming material,
- h. requirements for the supplier to notify AML of changes in product and/or process definition and, where required, obtain AML approval,
- i. right of access by AML, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- j. requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where

AML shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

#### **7.4.3 Verification of Purchased Product (as applicable)**

AML shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include

- a. obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),
- b. inspection and audit at supplier's premises,
- c. review of the required documentation,
- d. inspection of products upon receipt, and
- e. delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where AML utilizes test reports to verify purchased product, the data in those reports

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shall be acceptable per applicable specifications

Where AML delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where AML or its customer intends to perform verification at the supplier's premises, AML shall state the intended verification arrangements and method of product release in the purchasing information.

Were specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and AML's premises that subcontracted product conforms to specified requirements.

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

#### **7.4.3.5 Right of Entry**

AML will include right of entry provisions in any subcontract. These provisions will enable AML, the customer, the customer's customers and regulatory agencies to determine and verify the quality of work, records and material at any place, including the plant of the subcontractor.

#### **7.4.3.6 Requirements Flowdown**

AML will flow down quality system requirements to subcontractors to the extent necessary to ensure that characteristics not verifiable upon receipt are adequately controlled by the subcontractor.

### **7.5 Production (Inspection) and Service Operations**

#### **7.5.1 Control of Production (Inspection) and Service Provision**

Planning shall consider, as applicable,

- the establishment of process controls and development of control plans where key characteristics have been identified,
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- the design, manufacture (Does not apply to AML) and use of tooling so that variable measurements can be taken, particularly for key characteristics, and special processes (see 7.5.2).

AML shall plan and carry out inspection service provision under controlled conditions. Controlled conditions shall include, as applicable

- a) the availability of information that describes the characteristics of the product being inspected,
- b) the availability of work instructions, as necessary,

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- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,

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- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.
- g. accountability for all product being inspected ,
- h. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- i. provision for the prevention, detection, and removal of foreign objects,
- j. monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product being inspected quality, and
- k. criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

**7.5.1.1 Production (Inspection) Documentation:** Inspection operations shall be carried out in accordance with approved data. The inspection planning and the quality plan will be implemented through the work order. This data shall contain as necessary

- a) drawings, parts lists, process flow charts including inspection operations, customer documents (e.g., processing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and
- b) a list of specific or non-specific tools and numerical control (NC) inspection machine programs required and any specific instructions associated with their use.

**7.5.1.2 Control of Production (Inspection) Process Changes:** Persons authorized to approve changes to inspection processes shall be identified.

AML shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements. Changes affect inspection equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.

The results of changes to inspection processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product being inspected quality.

**7.5.1.3 Control of Inspection Equipment, Tools and Numerical Control (NC.) Inspection Machine Programs:** Inspection equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to inspection use shall include verification of the inspection capabilities by performing a probe check, or a measurement inspection check. Storage requirements, including periodic preservation/condition checks, shall be established for inspection equipment.

**7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities:** (Not applicable)

**7.5.1.5 Control of Service Operations.**

AML does not service any product as part of its normal business charter. Any servicing performed will be per customer written instructions and must be agreed

upon prior to the servicing being performed.

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**7.5.2 Validation of Processes for Production and Service Provision**

AML shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

AML shall establish arrangements for these processes including, as applicable:

- a) defined criteria for review and approval of the processes,  
- qualification and approval of special processes prior to use,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,  
control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

**7.5.3 Identification and Traceability**

Where appropriate, AML shall identify the product being inspected by suitable means throughout product (inspection) realization.

AML shall maintain the identification of the configuration of the product being inspected in order to identify any differences between the actual configuration and the agreed configuration.

AML shall identify the product being inspected status with respect to monitoring and measurement requirements.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), AML shall establish and document controls for the media.

Where traceability is a requirement, AML shall control and record the unique identification of the product being inspected (see 4.2.4)..

According to the level of traceability required by contract, regulatory, or other established requirement, AML's system shall provide for:

- a. identification to be maintained throughout the product being inspected life at AML
- b. all the products being inspected from the same batch of customer submitted material ;
- c. for an assembly being inspected, the identity of its components and those of the next higher assembly being inspected to be traced;
- d. for a given product being inspected, a sequential record of its inspection to be retrieved.

**7.5.4 Customer Product**

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AML shall exercise care with customer property while it is under AML's control or being used by AML. AML shall identify, verify, protect and safeguard customer property provided for use or incorporation control into the product being inspected. If any customer property is lost, damaged or otherwise found to be unsuitable for use,

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this shall be reported to the customer and records maintained (see 4.2.4)

NOTE Customer property can include intellectual property, including customer furnished data used for inspection.

**7.5.4.1 Notification and Authorization**

Supplier disposition of nonconforming customer-, customer's customer- or Government-furnished property requires authorization by the customer, or as otherwise provided in the contract.

**7.5.4.2 Receiving Inspection**

Purchaser-supplied material is submitted for inspection. The inspection records are maintained to give historical information of the material or the document's conformance.

**7.5.4.3 Nonconforming Material**

Material not meeting inspection specification requirements are rejected to the customer for their disposition.

**7.5.4.4 Storage**

AML will store all customer furnished supplied product to preclude damage, or per customer requirement.

**7.5.5 Preservation of Product being inspected**

**7.5.5.1 Handling, Storage, Packaging, Preservation and Delivery**

Preservation at AML shall be the prevention of damage and deterioration during all phases of the inspection, handling, packaging, and delivery processes. Provisions for the following will be addressed as required:

- a) Cleaning, of products being inspected will be per customer requirements;
- b) prevention, detection and removal of foreign objects;
- c) special handling and packaging of products being inspected will be per customer requirements;
- d) marking and labeling of both the product being inspected and shipping containers including safety warnings;
- e) shelf life control as required and stock rotation;

When contractually agreed upon AML takes on the responsibility for product delivery without degradation of product being inspected quality. Product identification will be per customer requirements.

**7.6 Control of measuring and monitoring devices**

AML shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product being inspected to determined requirements (see 7.2.1).

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AML shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE Monitoring and measuring devices include, but are not limited to: CMM's,

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inspection equipment both mechanical, visual, and electronic equipment. AML shall establish 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.

AML shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage..
- f) be recalled to a defined method when requiring calibration.

In addition, AML shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. AML shall take appropriate action on the equipment and any product being inspected affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

## **8 MEASUREMENT ANALYSIS and IMPROVEMENT**

### **8.1 General**

AML shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product being inspected,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

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

According to the nature of the product being inspected and depending on the specified requirements,

statistical techniques may be used to support:

- process control:
- selection and inspection of key characteristics;

- process capability measurements;
- statistical process control;
- design of experiment;
- inspection - matching sampling rate to the criticality of the product being inspected

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and to the process capability;

- failure mode and effect analysis.

## 8.2 Measuring and Monitoring

### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, AML shall monitor information relating to customer perception as to whether AML has met customer requirements. The methods for obtaining and using this information shall be determined.

### 8.2.2 Internal Audit

AML shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by AML, and
- b) is effectively implemented and maintained.

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

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Detailed tools and techniques shall be developed such as check sheets, process flowcharts,

or any similar method to support audit of the quality management system requirements.

The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall AML performance.

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

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance

### 8.2.3 Measurement and monitoring of processes

AML shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall

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demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product being inspected. In the event of process nonconformity, AML shall

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- a. take appropriate action to correct the nonconforming process,
- b. evaluate whether the process nonconformity has resulted in product being inspected nonconformity, and
- c. identify and control the nonconforming product being inspected in accordance with clause 8.3.

**8.2.4 Monitoring and Measurement of product being inspected**

AML shall monitor and measure the characteristics of the product being inspected to verify that the customer requirement have been met. This shall be carried out per customer planned arrangements (see 7.1).

When key characteristics have been identified, they shall be monitored and controlled per customer requirements.

AML shall not use sampling inspection as a means of product acceptance.

Evidence of conformity per customer requirement with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product being inspected release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

**8.2.4.1 Inspection Documentation:** Measurement requirements for product being inspected or service acceptance shall be documented. This documentation may be part of the inspection documentation, but shall include

- a) criteria for acceptance and/or rejection,
- b) where in the product/sequence measurement and testing operations are performed,
- c) a record of the measurement results, and
- d) type of measurement instruments required and any specific instructions associated with their use.

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

Where required to demonstrate product being inspected qualification AML shall ensure that records provide evidence that the product meets the defined requirements.

**8.2.4.2 First Article Inspection:** AML's system shall provide a process for the inspection, verification, and documentation of customer parts as required by the customer purchase order. Any change to a setup will be verified prior to continuation of the contracted inspection.

NOTE See (AS) (EN) (SJAC) 9102 for guidance.

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**8.3 Control of Nonconforming Product being inspected:**

AML shall ensure that product being inspected which does not conform to product requirements is identified and controlled per customer requirements. The controls and related responsibilities and authorities for dealing with nonconforming product being

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inspected shall be defined by customer contract.

This control will provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the customer as required.

AML shall ensure that product being inspected which does not conform to product requirements is identified and controlled per customer requirement.

*NOTE The term "nonconforming product" includes nonconforming product returned from a customer.*

AML's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming inspection or documentation and the process for approving personnel making these decision.

AML shall deal with nonconforming inspection or documentation by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.

AML shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- the product is inspected to customer design, or
- the nonconformity results in a departure from the contract requirements.

Records of the nature of nonconformities and any subsequent actions, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming inspection or documentation is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product being inspected documentation is detected after delivery or use has started, AML shall take action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, AML's system shall provide for timely reporting of delivered nonconforming inspection data that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer part numbers, quantity, and date(s) delivered. NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

**8.4 Analysis of data**

AML shall determine, collect and analyze 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 management system can be

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made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product being inspected requirements (see 7.2.1),
- c) characteristics and trends of inspection processes and including opportunities for preventive action, and
- d) suppliers.

**8.5 Improvement**

**8.5.1 Continual improvement**

AML shall continually improve 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**

AML shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a. reviewing nonconformities (including customer complaints),
- b. determining the causes of nonconformities
- c. evaluating the need for action to ensure that nonconformities do not recur,
- d. determining and implementing action needed,
- e. records of the results of action taken (see 4.2.4), and
- f. reviewing corrective action taken.
- g. flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
- h. specific actions where timely and/or effective corrective actions are not achieved.

**8.5.3 Preventive Action**

AML shall determine action to eliminate the cause of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a. determining potential nonconformities and their causes,
- b. evaluating the need for action to prevent occurrence of nonconformities,

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- c. determining and implementing action needed,
- d. records of results of action taken (see 4.2.4), and
- e. reviewing preventive action taken.

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## **QUALITY OBJECTIVES**

**AML shall reduce nonconformities in the inspection and documentation processes, by monitoring and measuring the output of those processes. AML shall increase productivity by reducing time and cost of internal documentation processes while increasing quality and efficiency.**

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