

Advanced Measurement Labs

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Quality Manual ISO9001:2015

AML	Quality Manual
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QAM Approval

Name	Title	Date
Romeo Arcinas	President Management Representative:	6/01/2017

Revision History

Revision	Issue Date	Description	Approval
"N/C":	10/01/03	WRITTEN TO ISO9001:2000	R.A.
"A":	07/01/2006	WRITTEN TO ISO 17025:2005 For customers requiring ISO17025 compliance	R.A.
"B":	12/01/2006	WRITTEN TO ISO 9001:2000	R.A.
"C":	07/01/09	Written to ISO 9001:2008 and AS9100 Revision "B" as Applicable	R.A.
"D":	07/01/2011	Upgraded Contract review process in new Flow Chart and added Supplier acceptance criteria by Supplier quality data from objective and reliable external sources, as determined by the Quality Manager (customers, quality management system or process certification bodies, organization approvals from government authorities,	R.A.
"E"	11-15-2014	Upgraded to correct references to AS9100 Revision "B" to AS9100 Revision "C" as Applicable	R.A.
"F"	6/01/2017	Written to ISO9001:2015 and applicable Elements of AS9100 Rev. D	R.A.

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Manual Number	Revision	Issued to	Remarks
1	F	Management Representative	Accept
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Advanced Measurement Lab a service company. Its only business is to inspect parts to customer specifications, consult and advise customers on technical issues. Advanced Measurement Labs, 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, (hereafter referred to as AML and applicable at its current locations, Tustin Ca.) AML is currently in compliance to ISO 9001:2015 and applicable elements of AS9100 Revision "D" (Design Activity Exclusion and all manufacturing), Regulatory, and Customer requirements. The policy of AML will be to apply this Quality Assurance Program to all Phases of our operation.

Written procedures and inspection instructions for implementation of the Quality Assurance Program will be established as dictated by the service performed and the level of instructions needed.

Procedures and necessary documentation for implementing the Quality Management System (hereafter referred to as Q.M.S.) are established, implemented, and maintained. Product or documentation created prior to the implementation of this QMS may not show evidence of compliance to ISO9001:2015 requirements.

The QMS is applicable when ISO9001:2015 (or customer equivalent) is specified by a customer or on a customer purchase order. This manual applies to all employees whose actions affect product quality. See AML scope (4.3 below).

2.0 Normative References

ISO9001:2015 and applicable customer requirements are normatively referenced in this document and are essential for its application.

3.0 Terms and Definitions

Counterfeit product: An unauthorized copy, imitation, substitute, or modified part, (e.g., material, part, and component) which is knowingly misrepresented as a specific genuine part of an original or authorized manufacturer.

Examples of counterfeit parts can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

Critical items: Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.

Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

Key characteristic: An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for controlling variation.

Product safety: The state in which a product can perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

Risk: Undesirable situation or circumstance that has a likelihood of occurring and a potentially negative consequence

Special requirements: Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, experience, and product or process maturity.

Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

4.0 Context of the Organization

4.1 Understanding AML and its Context: AML has determined external and internal issues that are relevant to the purpose and strategic direction of our business.

These issues include; Customer (Internal Teams) Satisfaction, Inspection capabilities to meet customer requirements, Work schedule to include short and long-term Capacity, Resources that include available trained and skilled labor, equipment software, and available controlled suppliers to meet customer demand (calibration, testing, services, and support inspection as required).

AML monitors and reviews information about these external and internal issues that affect our ability to achieve the intended result(s) of the QMS. The Monitoring may include customer satisfaction surveys, customer data and reports supporting inspection, work load schedules, training matrix, supplier control and supplier data reports,

4.2 Understanding the needs and expectations of interested parties: Due to their effect or potential effect on AML's ability to consistently provide inspection services that meet customer and applicable statutory and regulatory requirements, the AML determines the interested parties that are relevant to the QMS and the requirements of these interested parties that are relevant to the quality management system and are listed on the Interested Parties List.

This information is determined, monitored, and reviewed during AML's management review.

4.3 Determining the Scope of the QMS: AML has determined the boundaries and applicability of the quality management system, and considers the external and internal issues, the requirements of relevant interested parties, and the products and services that AML produces.

Advanced Measurement Labs performs inspection services to support customer requirements.

AML has determined that elements 8.3 to 8.3.6 concerning Design and Development activities are not applicable to AML the justification is that AML does not design any of the products that it produces for customers.

4.4 QMS and its Processes:

4.4.1 AML established, implemented, maintains, and continually improves the QMS, including the processes needed and their interactions, in accordance with ISO9001:2015 requirements. The QMS also addresses customer and applicable statutory and regulatory QMS requirements. AML determined the processes needed for the QMS and their application throughout AML and shall:

- a) determine the inputs required and the outputs expected from these processes using process diagrams.
- b) determine the sequence and interaction of these processes using flow chart data.
- c) determine and apply the criteria and methods (including monitoring, measurements, and related performance indicators) needed to ensure the effective operation and control of these processes.
AML monitors its main processes; Quality Objectives measure main processes and KPI's have been established to ensure process are meeting established goals.
- d) AML determines the resources needed for these processes and ensures their availability;
- e) assign the responsibilities and authorities for these processes using an Organization chart.
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1 using Failure Mode and Effect Analysis forms.
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results using monitoring data and Internal audits.
- h) improve the processes and the QMS using continual improvement plans and any applicable QMS documents.

4.4.2 AML:

- a) maintains documented information to support the operation of its processes. Quality procedures that define the applicable process controls are referenced within this manual.
- b) retains documented information to have confidence that the processes are being carried out as planned. AML has established and maintains documented information that includes:
- a general description of relevant interested parties is identified on the Management Review Template and reviewed a minimum of once per calendar year and as situations change.
 - the scope of the quality management system, including boundaries and applicability (see scope above).
 - a description of the processes needed for the QMS and their application throughout the organization using the QMS Process Interaction Chart.
 - the sequence and interaction of these processes using the QMS Process Interaction Chart.
 - The assignment of the responsibilities and authorities for these processes is defined on the organization chart.

5.0 Leadership

5.1 Leadership and Commitment: 5.1.1 General: AML will demonstrate its leadership and commitment to the QMS:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the QMS requirements into the organization's business processes;
- d) promoting the use of the process approach and risk-based thinking
- e) ensuring that the resources needed for the QMS are available;
- f) communicating the importance of effective quality management and of conforming to the QMS requirements;
- g) ensuring that the QMS achieves its intended results;
- h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2 Customer focus:

AML top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained;
- d) product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy: The Quality Policy reads as follows:

Advanced Measurement Labs strives to deliver the service and value that meet or exceed customer and regulatory requirements.

We commit to continually improve our QMS by establishing quality objectives, addressing risks and opportunities, and promoting ethical behavior.

5.2.1 Establishing the Quality Policy: The AML quality policy:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy: AML ensures that the quality policy:

- a) is available and maintained as documented information;
- b) is communicated, understood, and applied within the organization;
- c) is available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities, and authorities: AML has ensured that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.

This is listed on the organization chart and noted in the quality procedures. AML Top management has appointed the Inspection Lab Manager as the ISO9001:2015 Management Representative (Management Rep.).

The "Management Rep." has the organizational freedom and unrestricted access to top management to resolve quality management issues. Top management shall assign the responsibility and authority for:

- a. ensuring that the QMS conforms to the requirements of this International Standard;
- b. ensuring that the processes are delivering their intended outputs;
- c. reporting on the performance of the QMS and on opportunities for improvement (see 10.1), to top management;
- d. ensuring the promotion of customer focus throughout the organization;
- e. ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

Top management shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.

The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.

6.0 Planning

6.1 Actions to address Risks and Opportunities

6.1.1 When planning for the QMS, AML has considered both the "Understanding the Organization and Its Context" and "Understanding the Needs and Expectations of Interested Parties" issues and determined the risks and opportunities that need to be addressed to: give assurance that the QMS can achieve its intended result(s), enhance desirable effects, prevent, or reduce, undesired effects and achieve improvement.

6.1.2 AML will plan: Actions to address these risks and opportunities will be taken as applicable, integrate, and implement the actions into its QMS processes and be evaluated for effectiveness. **Controlled per procedure 8.1.1.**

6.2 Quality objectives and planning to achieve them

6.2.1 AML has established quality objectives at relevant functions, levels and processes needed for the QMS. Each main process has at least one measurable key performance indicator (KPI) established. These KPIs are assigned goals and AML monitors these goals periodically. These objectives are consistent with the Quality policy and applicable requirements are considered.

These objectives will be relevant to conformity of products and to enhancement of customer satisfaction. These objectives will be verbally communicated and posted around the shop. Objectives will be updated as appropriate. Management will act if these goals are not or will not be achieved. AML maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, AML determines what will be done, what resources will be required, who will be responsible, when it will be completed, and how the results will be evaluated.

6.3 Planning of changes: When management determines the need for changes to the quality management system, the changes will be carried out in a planned manner and will consider the purpose of the changes and their potential consequences, the integrity of the quality management system, the availability of resources, and the allocation or reallocation of responsibilities and authorities.

7.0 Support

7.1 Resources

7.1.1 General: AML will determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS. AML will consider:

- a) the capabilities of, and constraints on, existing internal resources; These resources will be defined by customer requirements, internal goals, quality objectives, and/or management objectives.
- b) What needs to be obtained from external providers? The external provider requirements will be documented on purchase orders issued by AML based on customer requirements and internal needs.

7.1.2 People: AML will determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes. Management will determine the employees required and their skill levels to ensure adequate control of all QMS operations and processes.

7.1.3 Infrastructure: AML will determine, provide, and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4 Environment for the operation of processes: AML will determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of the inspection services.

Consideration of human factors is the understanding of interactions between people, machines and each other and their impact on human performance (e.g. physical fitness, physiological characteristics, personality, stress, fatigue, distraction, communication, and attitude).

7.1.5 Monitoring and measuring resources Controlled per procedure 7.1.5.

7.1.6 Organizational knowledge: AML will determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge will be maintained as quality records and be made available to the extent necessary. This includes periodic assessment of the required Organizational Knowledge, employee training (cross-training, customer required training, industry training, process and task training, and training to internal processes), and documenting tasks as work-instructions. This will be documented on the Organizational Knowledge Log and reviewed during the Management Review meeting. All training shall be documented.

When addressing changing needs and trends, AML will consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. Assessments will determine the acceptance and/or effectivity of the changes.

7.2 Competence: The Competence requirements are controlled per procedure 7.2.

7.3 Awareness: The Awareness requirements are controlled per procedure 7.2.

7.4 Communication: AML will determine the internal and external communications relevant to the QMS, including:

- a) on what it will communicate; This may include customer quality, company quality, regulatory requirements, improvement, goals, or concerns.
- b) when to communicate; This may include scheduled communication through meetings or postings, or non-scheduled "As needed" communications.
- c) with whom to communicate; This may include group meetings by department, jobs, or as determined relevant by management, or individual employees.
- d) how to communicate; This may include scheduled communication through meetings or postings, or non-scheduled "As needed" communications.
- e) who communicates; This will be determined by management and may be communicated verbally.

7.5 Documented information (Includes 7.5.1, 7.5.2 and 7.5.3) is controlled per procedure 7.5.

8.0 Operation

8.1 Operational planning and control: Operational Planning will include as required customer, industry, and regulatory, requirements. **Controlled per procedure 8.1.**

8.1.1 Operational Risk Management: Controlled per procedure 8.1.1.

8.1.2 Configuration Management: Controlled per procedure 8.1.

8.1.3 Product Safety: Controlled per procedure 8.1.

8.1.4 Prevention of counterfeit product: Controlled per procedure 8.1.4.

8.2 Requirements for products and services: (Includes 8.2.1, 8.2.2, and 8.2.3) **Controlled per procedure 8.2.**

8.3 Design and development of products and services: N/A

8.4 Control of externally provided processes, products, and services. **Controlled per procedure 8.4.**

8.5 Inspection and service provision. **Controlled per procedure 8.5.**

8.5.1.3 Inspection process verification: **Controlled per procedure 8.5.1.**

8.5.2 Identification and traceability: AML will use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. As a minimum, all inspection jobs are traceable to a Work Orders number that is traceable to customer contract data.

AML will maintain the identification of the configuration of the products and services to identify any differences between the actual configuration and the required configuration per customer contract. AML will identify the status of outputs with respect to monitoring and measurement requirements throughout inspection and service provision. As a minimum, all inspection jobs are traceable to a job number that is traceable to customer contract data.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), AML will establish appropriate controls for the media. This will be documented on a log.

AML will control the unique identification of the outputs when traceability is a requirement, and will retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers. **Controlled per procedure 8.5.3.**

8.5.4 Preservation. **Controlled per procedure 8.5.4.**

8.5.5 Post-delivery activities: AML will meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, AML will consider statutory and regulatory requirements; the potential undesired consequences associated with its products and services; the nature, use and intended lifetime of its products and services; customer requirements; customer feedback; collection and analysis of in-service data (e.g., performance, reliability, lessons learned); control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul; controls required for work undertaken external to AML (e.g., off-site work); product / customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence). When problems are detected after delivery, AML will take appropriate action including investigation and reporting **per procedures 8.7 and 10.2 as applicable.**

8.5.6 Control of Changes: **Controlled per procedure 8.5.**

8.6 Release of products: AML will implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The planning shall note inspection/verification points at appropriate stages that are documented to ensure product compliance. **Controlled per procedure 8.5, section 4.1.10**

8.7 Control of Nonconforming Outputs, **Controlled per procedure 8.7.**

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General: AML will determine:

- a) what needs to be monitored and measured; the main processes identified, customer information, and other information determined by management.
- b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results.
This is accomplished by identifying key performance indicators (KPIs) for processes determined by management, assigning goals to these KPIs, and periodically analyzing results and evaluating the need for action.
- c) when the monitoring and measuring will be performed; annually or as determined by management.
- d) when the results from monitoring and measurement will be analyzed and evaluated.
This analysis may be used for product or process improvement, customer satisfaction, corrections and/or projects to upgrade the QMS as determined by management.

AML will evaluate the performance and the effectiveness of the QMS. AML will retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction: Controlled per procedure 9.1.2.

9.1.3 Analysis and evaluation: AML will analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis will be used to evaluate:

- a) conformity of products; Per KPI monitoring, management review results, quality objectives, etc.
- b) the degree of customer satisfaction; **Controlled per procedure 9.1.2.**
- c) the performance and effectiveness of the QMS is based on monitoring KPIs, internal audits, quality data, and customer information.
- d) if planning has been implemented effectively; this is determined during management review.
- e) the effectiveness of actions taken to address risks and opportunities; this is typically noted on the Improvement Log.
- f) the performance of external providers is reviewed and analyzed as KPIs.
- g) the need for improvements to the QMS are determined during the management review and Improvement Log.

9.2 Internal audit (Includes 9.2.1 and 9.2.2): Controlled per procedure 9.2

9.3 Management review

9.3.1 General: Top management will review AML's QMS, at planned intervals (once each calendar year as a minimum), to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of AML.

This review includes assessing its opportunities for improvement, the need for changes to the QMS including the company's Quality Policy and Objectives. Management review records are maintained.

9.3.2 Management review inputs: The management review will be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews; To include as applicable results of the actions, the goals, concerns, and any continued actions needed.
- b) changes in external and internal issues that are relevant to the QMS; To include as applicable customer, regulatory, corrections, improvements, or QMS changes.
- c) information on the performance and effectiveness of the QMS, including trends in:
 - customer satisfaction and feedback from relevant interested parties; Surveys, Quality and Delivery Data, Customer Complaints, and Customer Returns.
 - the extent to which quality objectives have been met; process performance and conformity of products and services; nonconformities and corrective actions; monitoring and measurement results; audit results; internal audits, process audits, 3rd-party audits, customer audits, and regulatory audits as applicable
 - the performance of external providers; on-time delivery performance;
 - the adequacy of resources;
 - the effectiveness of actions taken to address risks and opportunities (see 6.1);
 - and opportunities for improvement.

9.3.3 Management review outputs: The outputs of the management review will include decisions and actions related to:

- a) opportunities for improvement; Based on Monitoring, process audits, internal audits, quality data, and customer information.
- b) any need for changes to the QMS;
- c) resource needs; May include employees, equipment, facilities, suppliers, etc.
- d) risks identified; These may include departmental, processes, resources, external providers, and/or customer derived. **Controlled per procedure 8.1.1.**

AML will retain records as evidence of the results of management reviews.

10.0 Improvement

10.1 General: AML will determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These will include:

- a) improving products and services to meet requirements as well as to address future needs and expectations; This includes contracted customer requirements as determined through contract review. Planning, and capacity and capability determinations by management.
- b) correcting, preventing, or reducing undesired effects, and improving the performance and effectiveness of the QMS.

10.2 Nonconformity and Corrective Action: Controlled per procedure 10.2.

10.3 Continual Improvement: AML will continually improve the suitability, adequacy, and effectiveness of the QMS. AML will consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that will be addressed as part of continual improvement.

When formal continual improvement plans (CIP) are documented for a specific goal, the plans shall note the status, the goals to be achieved, applicable deadlines, and team members involved. AML will monitor the implementation of improvement activities and evaluate the effectiveness of the results.

CIPs will be documented on the Improvement Log and records will be maintained.

QMS PROCESS INTERACTION CHART

