Advanced Monolithic Systems, Inc.

Quality

Manual

Document #00-0001 Rev A

Advanced Monolithic Systems, Inc.

Quality Manual

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Quality Manual

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1.0 Scope

1.1 Introduction

This Quality Manual is issued and controlled by Advanced Monolithic Systems, Inc. (AMS) headquartered in Livermore, CA.

AMS is a designer and manufacturer of semiconductors specializing in the design and production of analog & power management integrated circuit devices.

This manual describes the AMS Quality System. It provides the authorization and control of related activities and their associated documentation.

1.2 Exclusions from ISO Standard

The AMS Quality Management System has been designed to be totally compliant to ISO 9001:2000 in all aspects that apply to the organization's operations and needs and does not detract from the ability or responsibility to provide product that fulfills customer and applicable regulatory requirements. The only elements within clause 7, Product Realization, of the standard to which an exception applies is in the application of process elements that deal with "service provisions." AMS products are of the nature that, once sold to customers, there are no servicing operations required to this product. The other is validation of processes (7.5.2). AMS products can all be verified by subsequent measurement or monitoring. These are addressed as "standard" AMS processes of product test and reliability monitoring, which are delineated in the applicable sections of this manual.

2.0 Applicability

The Quality Manual applies to all activities and personnel at the Livermore, CA, facility, as applicable to AMS products and the necessary internal and external processes that are defined and controlled.

"Factored Items" (3rd party designed and produced product with AMS name affixed) are <u>not</u> <u>applicable</u> to AMS. If a change ever occurred, however, the ISO Approval Certificate would not cover these products and the ISO Management Representative and Sales will be responsible to notify applicable customers that the ISO certification coverage does not apply.

3.0 Responsibility

This manual and the AMS Quality Policy are issued under the authority of the Chief Executive Officer/President of AMS. AMS documentation defines who has the responsibility for implementation of tasks to ensure conformance to the elements of the standard. The ISO Management Representative is responsible for ensuring that the Quality Management System is implemented and maintained to meet the requirements of this manual.

This manual is maintained by the ISO Management Representative. AMS departments maintain documented "Level II" process procedures, hereafter referred to as document numbers 00-01XX, and standard operating instructions detailing processes, methods and procedures necessary for implementation of the AMS Quality Management System. All of these documents, however, are controlled through the AMS document control system.

4.0   Quality Management System

4.1   General Requirements

AMS had developed a Quality Management System that meets the requirements of ISO 9001:2000 Standard and supports the AMS Quality Policy and objectives. This system delineates all of the processes necessary for a directed process approach that will:

a)   Identify system processes and their application within AMS.

b)   Provide for development of sequential/interactive processes within the system that are adequately communicated throughout AMS for their implementation.

c)   Describe those criteria and methods that define areas of responsibility to ensure effective: operation, control and continual improvement of the system.

d)   Ensure resources and information are made available to support operation and monitoring of the system.

e)   Monitor, measure and analyze the system to implement: action necessary to achieve planned results and continual improvement of these processes.

4.2   Documentation Requirements

AMS Quality Management System documentation adheres to the following structure:

Level I — AMS Quality Manual

Level II — Processes in flow chart format and as defined on Master Lists. (Documents in 00-01XX series.)

Level III — All Standard Operating Procedures and Instructions and forms, as defined on Master Lists.

Level IV — Completed records as defined in Level II documents as "QR" and in 00-0005, *Quality Records Matrix*.

To provide for internal communication and effectiveness of the utilization of the above documentation, they are all accessible through the AMS office network. Care should be exercised to ensure any copies made are always in accord with the revision status as shown on the Master Lists that are provided in "Corporate Quality Documents" of the Intranet home file.

4.2.1   General

The AMS Quality Management System documentation includes the following in compliance with ISO standard requirements:

a) Quality Policy & Objectives (Ref. paragraph 5.3.)

b) Quality Manual (Ref. paragraph 4.2.2.)

c) Documented procedures required by the ISO standard and, as needed, to ensure effective planning, operation and control of AMS processes. (Ref. paragraph 4.2.)

d) Quality records (Ref. paragraph 4.2.4.)

4.2.2   Quality Manual

The requirements contained within the quality manual are compliant with ISO 9001:2000 — *Quality management systems – Requirements*. AMS documentation identifies requirements to be met and specifies when, where and how these requirements are fulfilled. These are referenced herein in this manual. The quality manual is released through Document Control after necessary management approvals are obtained on the document release. It is thereafter maintained as a controlled document. Exclusion from ISO 9001:2000 requirements are as stated in paragraph 1.2 of this manual.

4.2.3   Control of Documents

4.2.3.1   General

Documented processes are developed to maintain control of all documents and data.

AMS acknowledges acceptance of customer-imposed requirements, specifications and standards. Customer and vendor documents are recorded and controlled upon receipt.

Document Control is responsible for making documents available at their points of use. The AMS NETWORK will be utilized to maintain and distribute master lists and make documents accessible. This is a secured file that is only accessible to Document Control for changes. "Hard copy" documents not maintained in the NETWORK will be controlled by Document Control. If (hard copy) paper documents are issued, Document Control indicates these controlled/distributed documents using ink-stamped copies. Documents held in the secured files within Document Control are considered as masters and do not require ink-stamp identification. AMS personnel have been instructed to consider unstamped copies as uncontrolled documents, which must be verified against the respective master list for current revision status.

Product proposal documents are considered to be preliminary working copies and, as such, are not required to be under document control.

4.2.3.2   Document and Data Approval, Issue and Revision

AMS uses qualified personnel for writing/creating and revising documentation and recommending the peer/management personnel whom are required for review and approval. Document owners, department managers and/or Document Control selects the personnel to review and approve the documents and the distribution required. For processes developed and implemented for all of the various elements of document control activities, the following shall be followed:

00-0110, *Document Control*; 00-0111, *Test Hardware and Software Control*; 00-0112, *Design Data Control*; 00-0113, *Design Rule Document Control*; 00-0114, *MIS Network Control*; and 00-0137, *Product Data Sheet Control*.

Controlled distribution of up-to-date revisions (so dated and revision numbered) are issued to the individual distributes or location(s) as indicated on a distribution list, as applicable. Obsolete revision documents are either destroyed or marked "*History*," "*For Reference Only*" or "*Revised*."

4.2.3.3   Data Back Up

Back ups of networked data files are performed on a weekly basis, as a minimum. Individual desktop data files are backed up on an "as needed" basis.

4.2.4   Control of Records

Legible quality records are generated, collected and maintained by AMS in accordance with established procedures (see Doc. #00-0131, *Control of Quality Records*). These records demonstrate the achievement of the required quality management activities and the effective operation of the Quality Management System. Specific records are listed in the *Quality Records Matrix* (Doc. #00-0005) and are designated in the Level II documents that define the AMS processes.

The Quality Records Matrix provides a list of each type of quality record, the location of the active and archived records, the method of indexing, and the minimum storage time. Contractual agreements, as applicable, are used as a basis of establishing quality records retention requirements and/or providing requested records to customers.

Storage of records is in a suitable environment that prevents damage, deterioration and loss. These records are readily retrievable from the location(s) identified in the Matrix. Records in an electronic media are controlled in accordance with the document and data control requirements of paragraph 4.2.3.

NOTE: The terms "records" in the ISO standard and "quality records" as used in AMS documentation is deemed to be synonymous in that they are both intended to provide objective evidence of conformity to the requirements of the quality management system (i.e., audit trail).

5.0 Management Responsibility

5.1 Management Commitment

Chief Executive Officer/ President and all management at AMS have endorsed and are committed to the Quality Management System as presented in this Quality Manual. This commitment is not limited to the initial development of this system, but to its continual improvement through the implementation of necessary management responsibilities. There are many activities encompassed within the scope of these responsibilities, but the primary ones that are necessary to achieve our quality objectives are:

a) Communicating to all AMS personnel the importance of meeting customer, regulatory and/or legal requirements. This is emphasized in the "ISO Awareness Training" (Doc. #03-0002) that is required of all AMS employees in their orientation training.

b) The establishment of an AMS quality policy and quality objectives. These are stated in paragraph 5.3 of this document.

c) Conducting management reviews to review the Quality Management System. This is further delineated in paragraph 5.6 of this document.

d) Providing resources to achieve all of the AMS goals and objectives, customer requirements and a structure for preventive measures to be implemented and for continual improvement activities.

5.2 Customer Focus

The AMS Quality Management System provides specific direction toward ensuring that customer requirements are determined and that these requirements are addressed. Implementation of customer-related processes, as defined in paragraph 7.2 of this document, are to be performed with the aim of meeting AMS Quality Policy of: *achieving complete customer satisfaction*. This shall include, where applicable, any regulatory or legal requirements that may be imposed. The management review process, as further addressed in paragraph 5.6 of this document, will provide added emphasis toward ensuring that an acceptable level of customer satisfaction is being achieved.

5.3   Quality Policy

Advanced Monolithic Systems, Inc. Quality Policy

> Advanced Monolithic Systems, Inc. is dedicated toward achieving:
> defect-free performance and complete customer satisfaction.

In support of the Quality Policy, the following quality objectives are applicable to AMS operations:

- To provide excellent semiconductor product design, manufacturing and related services for our worldwide customer base.
- To initiate and maintain mutually beneficial long-term partnerships with both our suppliers and our customers.
- Dedicate AMS resources within every facet of the company to achieve a culture of continuous improvement with objectives of assuring customer satisfaction and driving toward the goal of defect-free performance in everything that we do.

The Chief Executive Officer/President and all management at AMS have endorsed the Quality Policy as an effective statement, commensurate with AMS purpose.

Each functional organization ensures that personnel at all levels are fully knowledgeable of the Company Quality Policy.

The processes contained within the AMS Quality Management System provide for review of quality policy and objectives for performance and continuing suitability. (Ref. paragraph 5.6.)

5.4 Planning

5.4.1 Quality Objectives

The CEO/President and his staff shall establish measurable quality objectives on a continuing basis as a part of the management review process. These objectives, results of attaining these objectives and actions taken, shall also be part of the management review quality records.

Actions taken as a result of the review of these measures may take the form of corrective actions, preventive actions or revising goals for purpose of continuous improvement efforts. These may relate to any of the internal processes that are inherent to the Quality Management System or to address ongoing activities that will impact requirements to attain customer satisfaction.

5.4.2 Quality Management System Planning

A comprehensive system has been established through the development of the necessary Level II process documents. These documents provide the necessary part of providing the plans for implementation of all of the processes inherent in the AMS Quality Management System. These are delineated as follows:

00-0101 Plan for implementation of Management Reviews.

00-0102 & -0103 Plan for implementation of customer communication requirements.

00-0104 through 0108 Design-related activity plans and flow.

00-0109 Design planning and implementation relative to design changes.

00-0110 through –0114 and –0137 Document Control plans for implementation relative to: Documentation, Test Hardware & Software, Design Data, Design Rules, MIS electronic files and Product Data Sheets.

00-0115, -0116, -0135 & -0138 Supplier control plans related to selection and review.

00-0117 & –0140 Planned activities for procurement functions.

00-0118 Plan for implementing the control of customer-supplied material.

00-0119 Identification and traceability plan and flow.

00-0120 & -0121 Pre-Production/production plans and flow.

00-0122, -0123, and -0124 Inspection and test planning and implementation flow.

00-0125 Calibration implementation plans.

00-0127 & -0128   Nonconforming product control planning and implementation flow.

00-0129 Corrective/Preventive Action implementation plans.

00-0130 Shipping functions planning and flow.

00-0131 Plan for the control of quality records.

00-0132 & -0136 Plan for conducting internal audits.

00-0133 Plan and flow for conducting employee training.

00-0134 Planned method for measurement of processes and product and analysis of data.

00-0139 Planned activities related to customer satisfaction determination.

5.5   Responsibility, Authority and Communication

5.5.1   Responsibility and Authority

AMS management has defined the responsibilities and authority to its employees in organizational charts, procedures and work instructions as appropriate. This authority includes, but is not limited to, the freedom and responsibility to identify, record and begin actions necessary to prevent or correct non-conforming conditions, products and processes. (Refer to Doc. #00-0002, *Corporate Management*, AMS organization chart.)

Personnel at all levels are empowered with the responsibility to identify suspect nonconforming situations so that they may be addressed in accordance with applicable procedures.

AMS management encourages all employees to recommend or provide preventive or correction action solutions through approved channels.

Communication of the Quality Management System shall be provided to all AMS employees via EMAIL notification and made available through the AMS communication system (NETWORK).

5.5.2 Management Representative

The Director of Quality Assurance is the appointed ISO Management Representative responsible for ensuring compliance to ISO 9001, reporting directly to the Chief Executive Officer/President of AMS. Responsibilities and authority given to the Management Representative are to:

— Ensure that the processes of the Quality Management System are established, implemented and maintained. Delegation of process maintenance is delegated to process owners, as identified on process flow documents, but all changes must be reviewed by the Management Representative before being revised to ensure ISO conformance.

— Reporting to top management on the performance and any need for improvement of the Quality Management System. As a minimum, this shall be done at the scheduled management reviews as outlined in paragraph 5.6.

— Ensure the promoting of customer requirements throughout the organization.

5.5.3 Internal Communication

Communication between various levels within AMS shall be maintained to provide for information regarding the Quality Management System processes and their effectiveness. As a minimum it will consist of:

a) Defining the system through the Quality Manual (paragraph 4.2.2) and related Level II/Level III documents that delineate system process details, as required.

b) Establishing and maintaining a communications network (INTRANET) that provides for control of documents in use and their availability to all users.

c) Providing ongoing communication regarding the effectiveness of processes that make up the quality management system. These are further outlined in paragraph 5.6, Management Reviews and paragraph 8.0, Measurement, Analysis and Improvement.

d) Provide intra-company wide communication to all employees via e-mail notification of the Quality Management System effectiveness relative to meeting designated performance indicators in attaining quality policy goals and objectives.

5.6   Management Review

5.6.1   General

Management reviews the entire Quality Management System to include the elements as outlined in sections 5.6.2, Review Input, and 5.6.3, Review Output, of this manual.

Management review is further documented in Doc. #00-0101, *Management Review*. The results of reviews are documented in management review meeting minutes. Implementation of any resulting actions is verified by the Management Representative or other designee. The Management Representative maintains the records of management reviews in accordance with section 4.2.4 of this manual.

5.6.2   Review Input

Agenda for the management reviews shall include AMS to assess current performance and improvement opportunities. These are as delineated in process Doc. #00-0101, *Management Review*. The objectives of these reviews are to ensure suitability, adequacy and effectiveness of the Quality Management System including the AMS Quality Policy and objectives (paragraph 5.3) to determine whether there is a need for change. Measurable elements shall be used for this review for management-designated activities.

5.6.3   Review Output

The meeting minutes shall provide a record of all of the agenda input information presented and will also address improvement needs to: the Quality Management System/processes and to product relative to customer requirements. In addition, resource needs will be addressed if action is necessary to meet quality system, customer and/or regulatory requirements. Review outputs and their subsequent status shall be used in successive management reviews as a means of continued system assessment.

6.0 Resource Management

6.1 Provision of Resources

AMS management of resources is controlled within the budgeting cycle occurring annually. Department/section managers have the opportunity to request required resources that are necessary to implement and/or improve the Quality Management System or to address needs to achieve customer satisfaction. These include equipment as well as human resources. If special needs arise during the course of the year, between budget cycles, budget allocations are reviewed with top management in order to make necessary adjustments.

6.2 Human Resources

The responsibility for obtaining competent, qualified personnel is a joint responsibility of departmental managers and the Human Resources department.

6.2.1 General

The competency of assigned personnel shall be addressed on the basis of determining applicable education, training, skills and experience required. Training records for specific job responsibilities shall be used by requisitioning managers to document minimum job entry requirements. These may be used by Human Resource management along with job requisitions to obtain potential candidates.

6.2.2 Competence, Awareness and Training

All AMS employees, including temporary employees who could affect quality, receive overview training on the ISO 9001 Standard and the AMS Quality Management System. (Ref. paragraph 5.1.)

The methods employed in the training process (see Doc. #00-0133, *Training*) for assessing required skills, identifying, planning, conducting and documenting employee training activities include:

- Identifying specific skills for jobs, delineating tasks required, and communicating their relevance to achieve quality objectives.
- Defining training needed to bring employees to the required skill level.
- Performing the training and keeping records.
- Periodic retraining (including re-certification, where required).

As a minimum, supervisors and managers initially review training and experience needs to ensure that qualified personnel are performing assigned tasks and annually to assess ongoing training needs. Effectiveness of prior training is taken into account when making determinations of ongoing training needs and conducting performance reviews.

6.3 Infrastructure

AMS management is committed to provide and maintain suitable facilities that are necessary to implement the Quality Management System that will achieve conformity of product. These shall include: office areas and labs with adequate space to fulfill job requirements and equipment/hardware/software that currently exists and is defined as needed in annual budgeting cycles. In addition, the supporting services for production such as: sub-contract suppliers, failure analysis laboratories, etc. shall be obtained and utilized so as to obtain acceptable product to satisfy customer expectations. The maintenance of equipment that is needed to achieve the conformity of product is addressed in Doc. #00-0125 that delineates the process of calibration and preventive maintenance.

6.4 Work Environment

AMS management is committed to: establish, provide and maintain an infrastructure that is needed to comply with product requirements. Due to the nature of AMS operations, this is predominantly related to office, laboratory or storage areas where standard heating/cooling systems are employed and maintained. Safety committees are established to address any employee safety issue. Where chemicals may be used, Material Safety Data Sheets are maintained to provide instruction relative to physical and environmental issues.

In maintaining an acceptable work environment, AMS is committed to maintain its facilities in a safe and healthy manner that is in compliance with all applicable laws and regulations.

AMS complies with applicable environmental laws and regulations regarding hazardous materials, air emissions, and waste water discharges, including those regarding the manufacture, transportation, storage, disposal, and release to the environment of such materials. All of the AMS suppliers providing resalable product are required to provide to AMS those certifications attesting that they are also in compliance with these environmental regulations. Quality Assurance maintains the certifications as quality records.

7.0 Product Realization

7.1 Planning of Product Realization

Quality plans for product realization have been prepared in the form of collaborative processes involving many functions and departments. These are in the form of Level II Process Flow charts that address the requirements and interactive needs. These are further delineated in each of the appropriate sections of 7.0 and fully referenced in paragraph 5.4.2 to list all of the Quality Management System process documents.

The quality planning elements specifically determine quality objectives for products; the need for processes, facilities, documentation and other resources required for product realization; product verification and validation, monitoring, inspection and test activities; criteria for product acceptability; and the records to demonstrate product and process conformance.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

AMS has documented procedures that provide for the determination/identification of customer requirements, to include those that are not specified, but are necessary for intended use or compliance with applicable laws and regulations. It is recognized that in order to achieve customer satisfaction objectives, the customer requirements must be determined and identified. Typically, customer requirements shall be recorded to include such items as: availability, product description, delivery requirements and any other supportive activity that is required to satisfy AMS requirements.

Reviews of customer specifications shall be performed when received and any requirements documented for implementation, as applicable. These may take the form of Quality Assurance Instructions (QAIs), standard comments for specific customer orders, instructions for design implementation or the use of Industry Standards for: design, product fabrication, validation (characterization) and/or verification (qualification) processes (i.e., JEDEC Standards, EIC/JESD Standards, etc.). Records of customer documentation are maintained on the INTRANET file, which defines customer name, applicable documents received and revision/date, and are accessible to all AMS personnel requiring this information. Original documents are retained in Document Control files.

7.2.2 Review of Requirements Related to the Product

AMS has documented procedures that define the review process (see Doc. #00-0102, *Customer Requirements and Communications* and Doc. #00-0103, *Order Entry*). AMS review shall ensure that:

- the requirements are adequately defined and documented,
- the Company has the resources to meet the requirements, and that
- any differences between the contract and the tendered quotation are resolved to the mutual satisfaction of the involved parties before formal acceptance of the contract, and that
- in the event of product/contract requirement amendments, that appropriate notification is given to affected departments within AMS and that relevant documentation is revised.

Record requirements from these reviews are shown on the quote, e-mail, the Order Acknowledgement and/or within the AMS Business/MRP system, as applicable.

7.2.3 Customer Communication

AMS recognizes the necessity for customer communication and feedback as a major contributing element of customer satisfaction. Responsiveness is a key indicator of AMS commitment to customer needs. The implementation of customer responses as related to order issues, as well as those not specifically related to an order of product, are addressed in AMS documents 00-0102 and 00-0103. In order to ensure the validity of production information provided to customers, product data sheets are maintained and made available on a WEB page and controlled by Doc. #00-0137, *Product Data Sheet Control*.

7.3 Design and Development

7.3.1 Design and Development Planning

AMS reviews and evaluates design requirements to ensure that the products it designs and develops meet or exceed customer specifications. (See Doc. #00-0102, *Customer Requirements and Communications*; Doc. #00-0104, *Design*; Doc. #00-0105, *Test Development*; Doc. #00-0106, *Prototyping*; Doc. #00-0107, *Design Characterization*; Doc. #00-0108, *Design Qualification*; Doc. #00-0109, *Engineering Change*.)

In the course of addressing technical, logistical/managerial and financial concerns that impact its design-process activities, AMS consistently exercises its organizational interfaces. (See Doc. #00-0104, *Design*.) Planning shall be maintained to its most current status, as appropriate, as the design activity progresses. This is necessary to communicate with responsible groups in their implementation of activities related to the design or development processes such as: test, design verification (characterization), design validation (qualification), procurement of prototypes, etc.

7.3.2 Design and Development Inputs

AMS identifies design input and any applicable statutory or regulatory requirements during contract review, AMS/customer meetings, marketing surveys or inputs from AMS employees. Ambiguous, conflicting, changing and unclear/incomplete requirements are clarified by reviews of the design at various stages of the designing process. Design requirements are amended to accurately capture all pertinent design input information. (See Doc. #00-0104, *Design*.)

7.3.3 Design and Development Outputs

AMS captures design-output data in design review minutes and customer reviews, as needed. These reviews are performed specifically to verify that design-output meets or exceeds design-input requirements. Acceptance criteria shall be based on the test development, product characterization and qualification plans, which shall be implemented per paragraphs 7.3.5 and 7.3.6. These plans will include, as required, those characteristics of the design that are crucial to the safe and proper functioning of the product. The design output review must occur before the design is permitted to progress further in the product release process. This review will ascertain that information is available to define product acceptance criteria and that all of the information necessary for production of the device has been provided.

7.3.4 Design and Development Review

AMS design teams review every design at key times based on the design plan and design review checklist. (See Doc. #00-0104, *Design*.) Design review includes: manufacturing requirements, cost/performance/risk trade-offs, test methodology and conditions, guardbands, and data from previous designs. *Design Characterization* (Doc. #00-0107) and *Design Qualification* (Doc. #00-0108) data results are reviewed by appropriate personnel representing all concerned departmental functions to evaluate the designed products' ability to fulfill design input requirements. In the event of problems being uncovered, follow-up proposals and actions will be identified as a part of the design review minutes. Records of these design reviews shall be maintained by the responsible Business Unit to document these reviews.

7.3.5 Design and Development Verification

AMS verifies product designs by performing in-depth "bench" tests that assess the product's output compliance to the design specifications. (See Doc. #00-0107, *Design Characterization*.)

7.3.6 Design and Development Validation

AMS verifies product designs by performing laboratory tests to confirm that the product is capable of meeting the requirements for the intended use of the product. (See Doc. #00-0108, *Design Qualification*.)

7.3.7 Control of Design and Development Changes

All design changes either initiated by AMS or requested by the customer are reviewed and implemented per Doc. #00-0109, *Engineering Change*. Changes that impact device form, fit or function shall have applicable verification and/or validation testing performed. This data shall be included in process change notice (PCN) documents per Doc. #11-0005.

7.4   Purchasing

7.4.1   Purchasing Process

AMS uses documented processes to control its purchasing activities. The process is defined in Doc. #00-0115, *Purchasing*, that delineates elements of: supplier selection, Approved Vendor List (AVL) generation, issuance of purchase orders and other tasks related to the Purchasing process. Doc. #00-0116, *Supplier Approval*, provides direction for implementation of those activities that are necessary to evaluate and select suppliers with the ability to supply product meeting AMS requirements. For the purchase of product that is procured to meet IC prototyping needs, the process, as defined in Doc. #00-0140, *Purchasing IC Products - Prototypes*, is applied; and for IC Production, Doc. #00-0117, *Purchasing IC Products*.

For periodic reviews of supplier performance, evaluations that are conducted are outlined in Doc. #00-0135, *Supplier Review* and in Doc. #00-0138, *Reliability Data Review & Monitors*. These provide for adequate assessment of suppliers and determination of their acceptability to remain on the AVL as a source of supply to AMS.

7.4.2   Purchasing Information

The information necessary for suppliers to implement AMS purchase orders are provided either in the specific order or transmitted as controlled documents that are retained by the suppliers and used, as applicable, for orders being placed. Information that is provided to suppliers is referred to in Doc. #00-0106, *Prototyping*, Doc. #00-0120, *Pre-Production*, and Doc. #00-0121, *Production*. Records of documents issued and their revision status are maintained by Document Control.

7.4.3   Verification of Purchased Product

The verification of product is performed in accordance with Doc. #00-0122, *Receiving Inspection*; Doc. #00-0123, *Vendor Testing* or Doc. #00-0124, *In-House Testing* as is applicable to the purchase order delivery requirements. These processes for verification apply to: AMS-US office. Where the verification elements of receiving inspection and test shall be performed by them using their processes, which are coordinated to include: AMS and AMS customer requirements. In the event that AMS or customer verification of product is required at the sub-contracting source(s), this shall be invoked by means of a supplier notification that would delineate verification arrangements and product release conditions.

7.5 Production

7.5.1 Control of Production

AMS maintains documentation for the control of processes that directly affect product quality. Specifically, major processes affecting production include: Doc. #00-0120; *Pre-Production* and Doc. #00-0121, *Production*.

Due to the nature of procurement of AMS product, it is necessary to use only qualified sources for the fabrication, assembly and test of AMS products. Process control elements are assessed and evaluated in the supplier selection process and include suitability of the subcontracted source from the standpoint of production capabilities and controls implemented, equipment, and work environment. The supplier selection process is initiated to constitute, as a minimum, the approval of processes, equipment and the workmanship criteria that is applicable to the services performed and the product involved.

AMS product test processes are performed in an acceptable work environment, utilizing approved hardware and software as evaluated and issued for production test through the Test Development process. (Ref. Doc. #00-0105, *Test Development*.) Product acceptance criteria is as defined by the applicable Level III documentation that is released at the time of production release of the product and is used in test per Doc. #00-0123, *Vendor Testing* or Doc. #00-0124, *In-House Testing*.

To ensure efficient and safe equipment operation, AMS utilizes a preventive maintenance program for its test equipment, which is included in the calibration of equipment activity.

The nature of AMS product does not require special monitoring and control of process parameters to isolate processing deficiencies that are undetectable by acceptance test of the product. "Special monitoring" does not exclude those process controls, however, that are implemented by the fab and assembly sub-contractors that are an integral part of their approved production processes.

7.5.2 Validation of Processes for Production

This requirement of the ISO standard is not applicable to AMS as stipulated in paragraph 1.2 of this quality manual.

7.5.3 Identification and Traceability

Identification and traceability requirements are established and procedures are in place to ensure compliance.

Product is identified with a sales part number at the start of design of the part and is used in conjunction with a cross-referenced manufacturing part number for subsequent part and manufacturing activities. The AMS manufacturing part number is used by the supplier during production. For additional traceability to the process, wafer lot numbers and assembly date codes are assigned by the subcontractors at the start of their respective production processes. The product is tracked through the various stages of processing, storage and distribution using these assigned identifications. The identification is recorded on all documents, such as process, inspection and test records as defined in appropriate procedures. The supplier has the responsibility to supply AMS with inputs of traceability records for all IC product material. Documents related to product handled by AMS are maintained by AMS in the appropriate lot folders and/or records maintained within the MRP system. (See Doc. #00-0119, *Product Identification and Traceability*.

The status of material inspection and test is maintained by each approved supplier and within the AMS MRP System. When product is tested at AMS, controls are provided to give positive identification of inspection and test status. Controls include: color-coded tubes/trays, use of travelers, physical location designations and updates to the MRP System.

7.5.4 Customer Property

AMS by the nature of its business does not utilize customer-supplied product or tooling. In the event the customers supply product, AMS would handle the product as any other purchased product, as long as both are in concurrence with the tendered contract. If not, the contract requirements would prevail. AMS does occasionally receive customer-supplied items for the purpose of evaluation. These samples are handled per Doc. #00-0118, *Control of Customer-Supplied Items*.

7.5.5　Preservation of Product

The methods used for handling, storing, packaging, preserving and delivery of material to ensure it is not damaged and that it is maintained in an acceptable condition is documented in various processes, procedures and AMS Quality Assurance Instructions (Q.A.I.s). Damaged or nonconforming material is controlled and dispositioned according to established procedures as described in Doc. #00-0127, *Control of Nonconforming Product*.

−　Handling.　　The necessary resources have been made available for the proper and safe handling of material.

−　Storage.　　Areas within Receiving, Finished Goods and work-in-process are designated for storage of material. Receipt and transfer of material is performed by authorized personnel according to established procedures.

　　　　　　　Examination of stored material occurs at appropriate intervals. This examination determines if any deterioration has occurred and assesses the continued usability of the item(s).

−　Packaging.　　Industry standard practices establishes the packaging and identification requirements for material. Special customer requirements are reflected in Quality Assurance Instructions (Q.A.I.s). Prior to shipment, material is identified and packed to meet AMS requirements to prevent damage. (See Doc. #00-0130, *Shipping*.)

−　Delivery.　　Material is delivered to customers using customer-designated carriers or AMS-approved carriers, as applicable.

7.6   Control of Monitoring and Measuring Devices

Measuring and Test Equipment

All measuring and test equipment is maintained and calibrated on a pre-scheduled basis. Details are documented in: Doc. #00-0125, *Calibration, Test Equipment*.

AMS utilizes a positive recall calibration schedule to ensure identified equipment is calibrated. Copies of calibration records for each piece of equipment are maintained per section 5.5.7 of this manual. Calibration data is evaluated for drift in calibration parameters as needed. The accuracy and precision of measuring, test, and inspection equipment is addressed by the user or person(s) delegated with the responsibility for equipment selection prior to the intended use ensuring measurement integrity.

Inspection and measuring equipment is selected for use based on the accuracy required for the specific inspection/measurement being taken.

A complete inventory of measuring, inspection and test equipment used within AMS is maintained on a Calibration List at each AMS US office.

Outside calibration laboratories, when used, are certified by approved facilities having standards traceable to the National Institute of Standards and Technology (NIST). Other sources, such as manufacturers' reps servicing testers for calibration and/or preventive maintenance (PM), shall have recorded procedures to perform these activities.

Evaluation of results takes place after calibrations are performed to check the adequacy of the calibration intervals presently in use.

All measuring, test, and inspection equipment bear a tag, sticker or other identification showing calibration status.

New equipment used for measurement or inspection receives an initial calibration or verification before release for use.

Where equipment is found to be out of calibration, an analysis is initiated to assess impact on previously tested product and a Corrective Action Request (CAR) is issued to initiate appropriate action.

At all times, during both handling and use of equipment, care is taken to ensure that damage is not sustained and that the calibrated accuracy of the equipment is not adversely affected. Equipment is handled, stored and used under suitable environmental conditions to sustain equipment integrity for its intended applications and use.

If required by customers or their representatives, the necessary technical data pertaining to applicable measuring/test equipment is available for the verification of its functional adequacy.

Employee-owned equipment is not used for inspection, test or acceptance of any product.

Software

The software that is developed for measurement or monitoring use is validated prior to its release for pre-production or production use. (Ref. Doc. #00-0105, *Test Development*.)

If changes are required to test hardware and/or software, it is validated prior to its re-release for pre-production or production test use. (Ref. Doc. #00-0111, *Test Hardware and Software Control*.)

8.0 Measurement, Analysis and Improvement

8.1 General

AMS has the necessary methods in place to initiate those elements of measurements and analysis to facilitate the assessment of product conformance and to achieve improvement in whatever areas are deemed necessary within the Quality Management System. The specifically-planned activities to achieve these objectives are: Doc. #00-0101, *Management Review*, which is the primary function to assess the performance levels and make necessary decisions regarding improvement requirements. It also establishes improvement goals and objectives. Doc. #00-0139, *Customer Satisfaction Determination*, which provides an action plan to obtain information, analyze and take required action.

Doc. #00-0128, *Return Material Authorization*, which designates the plan of obtaining information regarding product acceptability and taking corrective and/or preventive action to improve detrimental conditions.

Doc. #00-0132, *Internal Audits* and Doc. #00-0136, *Resolution to Internal Audit Findings*, which provides a plan for continuous assessment of the quality management system to identify deficiencies that could impede meeting AMS objectives.

Doc. #00-0107, *Design Characterization*; Doc. #00-0135, *Supplier Review*; and Doc. #00-0138, *Reliability Data Review & Monitors*, which provides planned activities that are used to measure, monitor and take remedial action on both process and/or product deficiencies.

Doc. #00-0127, *Control of Nonconforming Product*, which provides for segregation of suspected unsatisfactory product and allows for evaluation and corrective/preventive action implementation.

Doc. #00-0134, *Statistical Techniques*, which provides a basic planning document for analysis purposes.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction is determined by means of customer communications and feedback. Major elements of this process are implemented through: Doc. #00-0102, *Customer Requirements and Communications*; Doc. #00-0128, *Return Material Authorization*; and Doc. #00-0139, *Customer Satisfaction Determination*. In the implementation and analysis of the resultant information, management reporting is initiated and action(s) taken that are necessary to either remedy customer dissatisfaction or further improve on levels of customer satisfaction.

8.2.2 Internal Audit

Internal quality audits are planned and performed using documented procedures. (See Doc. #00-0132, *Internal Audits*, and Doc. #00-0136, *Resolution to Internal Audit Findings*.) The audits are performed by trained personnel on areas of which they have no direct responsibility and can, therefore, conduct impartial, objective audits. The audits objectively evaluate the effectiveness of all aspects of the Quality Management System. Internal audits are scheduled on the basis of status and importance of the activities involved.

Supervision/management of the area audited is responsible for reviewing any findings found by the auditors and taking appropriate action to correct them. The Internal Quality Auditors review and verify actions taken to ensure adequate and effective corrective action of the findings. Findings, actions and closure are documented.

The Lead Auditor generates and distributes the audit report according to procedures. The ISO Management Representative provides internal audit report summaries to Executive Management for their review and assessment of the continued effectiveness of the Quality Management System and the determination and assignment of any remedial action that may be necessary.

8.2.3 Monitoring and Measurement of Processes

AMS activities related to the monitoring and measurement of realization processes address those elements of design and sub-contractor control, as applicable. Design monitoring is implemented through Doc. #00-0107, *Design Characterization* and Doc. #00-0108, *Design Qualification*. Measurement and monitoring of supplier processes is conducted through the analysis of data by the application of Doc. #00-0138, *Reliability Data Review & Monitors*. Statistical process control techniques are utilized as addressed in Doc. #00-0134, *Statistical Techniques*. Primary objectives are to: determine that processes have the ability to achieve planned results and to initiate corrective action if nonconformances are detected.

8.2.4   Monitoring and Measurement of Product

The product measurement and monitoring activities are conducted to ensure that product characteristics are maintained. As applicable to the production plan for devices that are fabricated (Ref. Doc. #00-0120, *Pre-Production* or Doc. #00-0121, *Production*), receiving inspection and tests are performed to verify acceptability. These activities are performed in accordance with: Doc. #00-0122, *Receiving Inspection*; Doc. #00-0123, *Vendor Testing* and/or Doc. #00-0124, *In-House Testing*.

8.3   Control of Nonconforming Product

AMS procedures ensure that items found to be non-conforming are clearly identified. The nonconforming items are segregated and action taken to prevent use, shipment or mixing with conforming products until properly dispositioned. (See Doc. #00-0127, *Control of Nonconforming Product*.) In any instance where a rework/retest is performed, it is re-inspected for acceptance prior to being directed to the next level.

AMS authorized personnel review and disposition nonconforming material and products according to one or more of the actions listed. Disposition results are documented as described in Doc. #00-0127. If required by contractual commitments, any product deviation or rework not conforming to specified requirements is to be reported to and approved by the customer before authorization to release for shipment.

If a nonconformity is detected after delivery, AMS will take those actions that are necessary, as appropriate, to the effects or potential effects of the nonconformance.

8.4   Analysis of Data

The various sections of this Quality Manual and their related process flow documents address the need for, and implementation of, analyzing data in order to achieve and measure the effectiveness of the Quality Management System in achieving the quality policy and objectives. It is necessary to be addressed in this manner since it is a collaborative process involving many departments and functions. Examples of data collection and analysis and how it is integrated into the overall Quality Management System are as delineated in the various following paragraphs of this Quality Manual.

- Paragraphs 7.3.5 and 7.3.6, Design Activities
- Paragraph 7.4.3, Verification of Purchased Product
- Paragraph 8.0, Activities Related to Analysis and Improvement

The use of Doc. #00-0134, *Statistical Techniques*, provides direction for application of various SPC methodologies for the analysis of data where it is advantageous to be utilized. Final use of the data analysis results may be in the generation of corrective/preventive action requests. A major agenda item for all management reviews (Ref. Doc. #00-0101) is analysis results.

8.5   Improvement

8.5.1   Continual Improvement

Continual improvement is not a discrete process or element of the Quality Management System, but rather a way of managing the system. The Quality Management System has all of the necessary elements of establishing the policy and objectives for quality, for implementing operational controls to achieve the objectives and for measuring the results. The basic methodology and plan is that if the results fail to meet the objectives, it is the fault of the system. Therefore, the system must be improved so that it becomes more effective in reaching the objectives. When the objectives are achieved, new objectives are set and the Quality Management System is improved to meet the new challenges.

Identification of continual improvement needs are determined by analyzing customer satisfaction information, product and process conformance data, supplier performance data, internal audit results, and other data and information relevant to quality performance. Management review considers all relevant information and defines priorities for improving the quality system. The corrective action and/or auditing processes are used to formally identify, respond to, verify acceptability of actions and track the corrective action requests or internal audit findings.

8.5.2   Corrective Action

The process utilized by AMS for the implementation of corrective action is as defined within Doc. #00-0129, *Corrective/Preventive Action*. This correction action process provides for: defining non-conformities, determining root cause, evaluating action to ensure non-recurrence and implementing, recording and reviewing actions taken. More detailed instructions related to the corrective action process are found in the AMS procedure Doc. #02-0010.

8.5.3   Preventive Action

Preventive action is defined as an action taken based on the observance of a systemic condition or the result of a corrective action where further action is deemed necessary to curtail the same or similar occurrences within other processes or realization activities.   Implementation of preventive action measures are as defined in Doc. #00-0129, *Corrective/Preventive Action*. The preventive action initiated is to be appropriate to the potential impact of the problem. Similar to the corrective action process, the process employed identifies potential nonconformities and their cause(s), determines and ensures implementation, and records and reviews preventive actions taken.

REVISION HISTORY AND DOCUMENT APPROVAL

Rev	Description	Date	ECR #
A	Initial Release	06/19/02	

QUALITY MANUAL APPROVAL

The release/change document, "Document Change Request," that is maintained in Document Control provides the approval signatures of: CEO/President, CFO, and management representatives from: Business Units, Sales, Engineering Services, Operations and Quality Assurance.