
INTRODUCTION

Renesas Electronics America Inc., based in Milpitas California, is a leader in the innovation of power management and precision analog ICs.

Renesas Electronics America Inc. (hereafter referred to as REA) has established market leadership in many of the most rigorous applications in the computing, consumer and industrial markets. The company supplies a full range of power IC solutions including battery management, computing power, display power, regulators, controllers, integrated FETs and power modules; as well as precision analog components such as amplifiers and buffers, proximity and light sensors, data converters, timing products, optoelectronics and interface products. As a major supplier to the automotive, military and aerospace industries, REA's product development methodologies reflect experience designing products to meet the highest standards for reliability and performance in challenging environments.

REA's quality management system documentation is written, implemented, and maintained to meet the most current requirements as applicable of ISO/TS 16949:2009 for select product flows, ISO 9001:2008 and MIL-PRF-38535. The systems have been certified to the applicable ISO 9001 systems since 1994 and to MIL-PRF-38535 requirements that include design since 1993. Internal specifications and the subsequent sections of the Quality Manual will only reference ISO/TS16949 and/or ISO 9001 as applicable without the date extension.

Purpose:

The purpose of this manual and the associated procedures is to describe the manner in which REA successfully operates with a reputation for quality and reliability using the processes described in ISO/TS 16949, ISO 9001 and MIL-PRF-38535. The sequence, interaction, and management of the processes that support our business are described in this manual along with basic policies for quality.

Written procedures which describe how operations and processes are performed to produce quality products and services have been developed and distributed to appropriate personnel to encourage consistent practices. This procedural support coupled with training and where necessary, detailed instructions, ensures that everyone knows and understands the processes that they are expected to perform.

We strive to continually improve our business practices as well as our documented quality management systems as a whole to satisfy our customers and operate our business efficiently and effectively. Defining our quality objectives, implementing improvement projects, and using our quality management system to support their implementation assures continual improvement in every aspect of the processes and operations. Through process monitoring and measurements, where appropriate, and the analysis of data collected, the degree to which our goals are met is determined.

The content of this manual is arranged to follow the structure of the ISO 9001 and ISO/TS16949 Standard. The systems encompass the 5 primary processes identified in the standards.(Clause 4.0 Document and Record Control, Clause 5.0 Management Responsibility, 6.0 Resource Management; Clause 7.0 Product Realization; Clause 8.0 Measurement, Analysis, and Improvement) The ISO/TS16949 adders are identified by (TS) in this document and do not in all cases apply to standard operations.



1.0 SCOPE

ISO 9001 applies to all worldwide operations involved in the marketing, design, development, manufacture, and delivery of semiconductor devices.

ISO/TS 16949 applies to the marketing, design, development, manufacture and delivery of select products/technology flows for automotive customer applications.

The certificate and scope statement for ISO 9001 is as follows:

Renesas Electronics America Inc.

Milpitas Design, Development and Operations Center
1001 Murphy Ranch Road, Milpitas, California 95035 USA

Palm Bay Design, Development, and Operations Center
1650 Robert J. Conlan Blvd., Palm Bay, FL 32905 USA

New Jersey Design and Development Center (formally known as North Branch)
440 US Highway 22 East, Suite 100, Bridgewater, NJ 08807 USA

North Carolina Design and Development Center
419 Davis Dr, Suite 300, Morrisville, NC 27560

Austin Design and Development Center
900 S. Capital of Texas Highway, Austin, Tx 78746

Tempe Design, Development and Operations Center
7855 S. River Parkway, #122, Tempe, Az. 85284

This certificate is valid for the following products/services:

The Design, Manufacture, Testing and support of Power Management and High Performance Analog
Integrated Circuits



Controlled Document

The scope statement for ISO/TS16949 is as follows

Renesas Electronics America Inc.

at

Milpitas Design, Development and Operations Center
1001 Murphy Ranch Road, Milpitas California 95035

Palm Bay Fabrication Center
1650 Robert J. Conlan Blvd., Palm Bay, FL 32905 USA

North Carolina Design and Development Center
419 Davis Dr, Suite 300, Morrisville, NC 27560

The Design and Manufacture of Power Management and High Performance Analog Integrated Circuits

Supporting Functions and Locations		
Name	Address	Scope
Sales	Renesas Electronics Europe GmbH Munich Office Karl-Hammerschmidt-Str. 42, 85609 Aschheim-Dornach, Germany Palm Bay, Florida Milpitas, California	Sales
Contract Review	Palm Bay, Florida	Contract Review and Finalization
Customer Satisfaction	Milpitas, California	Customer Satisfaction Calculations and Review.
Product Return Services	Palm Bay, Florida Milpitas, California	Tracking/Interface for Returned Product
Quality Services	Palm Bay, Florida 157 Hampshire Place Office Suit A-13-1, 157 Hampshire, No 1, Jalan Mayang Sari, 50450 Kuala Lumpur, Malaysia	Internal Audit Document Control Foundry Audits Supplier Control and Development
Lab Support <ul style="list-style-type: none"> • Stress Testing • Failure Analysis 	Palm Bay, Florida Lot 52986, Taman Meru Industrial Estate, Jelapang, P. O. Box 380, Ipoh, Perak, Malaysia	Analysis/Reliability Testing and Related
Design and Product Realization	Milpitas, California Palm Bay, Florida Morrisville, North Carolina	Product design and related product realization testing



Controlled Document

REA requires and verifies the ISO/TS 16949 certification/compliance of foundries and sub-contractors used for the manufacture of automotive products.

2.0 REFERENCE

The Quality Management System is based on the International Organization for Standardization (ISO) 9001 Quality Standards, including ISO 9001, ISO/TS 16949, and MIL-PRF-38535.

3.0 TERMS AND DEFINITIONS

Industry Standard Terms and Definitions Apply

4.0 QUALITY MANAGEMENT SYSTEM

REA has established, documented, implemented and maintains a Quality Management System that utilizes the ISO 9001, ISO/TS 16949 and MIL-PRF-38535 standards to continually improve the internal process and promote customer satisfaction.

4.1 General

4.1.1 Quality Management System Sequences, Interactions, and Outline

Appendixes A, and B contains the top level flow showing Key Processes and their sequence and interaction. The appendixes also shows the Management-Oriented Processes (MOPs), Customer-Oriented Processes (COPs) and Support Functions (SOPs)

The sequence of our primary processes is as follows:

- a) Order Fulfillment - Product Line Segment Management develops marketing forecasts. Sales provide quotations for current and potential clients, accepts orders and tracks fulfillment.
- b) Product Realization – A team concept is utilized in the design, development, release, production, testing, customer satisfaction and tracking of product from concept to release.

Management-Oriented Processes are:

- a) Business Planning– a process to plan and communicate our quality and business objectives.
- b) Business Management Review- a planning and management process used to ensure that quality requirements are planned and the quality management system is reviewed for adequacy. Results and process metrics are reviewed to ensure that quality objectives are met As a result of periodic reviews, any process may be changed in a controlled manner.
- c) Internal Auditing – a process to assist management in assuring that the quality management system remains compliant to the prescribed processes and is implemented as defined.
- d) Corrective and Preventive Action – a process to ensure that known and potential problems (including customer complaints) are addressed in an effective and timely fashion. As a result of this process, any process may be changed in a controlled manner.
- e) Customer Satisfaction – a process to collect data to measure customer satisfaction and generate improvement plans as applicable.

Support Functions are:

- a) **Quality and Reliability Assurance:** A group of processes, that ensures the quality/reliability of products through development, production and testing operations including customer use. These processes include but are not limited to Product Qualification, Product Return Analysis, Document and Records Control, Supplier Quality Management, and Non-conforming material.
- b) **Facilities** – Provides the infrastructure such as equipment, building and working environment needed for the organization to perform its functions, meet its business goals, and the needs and expectations of its customers.
- c) **IT** – Provides the systems needed for communications within the organization, storage and retrieval of data and information needed by the organization to conduct business and for personnel to fulfill their responsibilities.
- d) **Finance** – monitors, reports and helps drive improvement of the organization’s revenues and other financial metrics
- e) **Human Resources** – process to ensure that our personnel are adequately qualified and trained to perform the task assigned
- f) **Outsourced Control/Purchasing** – Control of outsourced processes e.g. wafer fab, assembly, test and materials are defined within the QMS system ensuring conformity to all requirements, including customer specific requirements.

Process interactions are noted as two-way dashed or dotted arrows in the Process Map (Appendix A).

Appendix C (ISO/TS16949) and Appendix D (ISO 9001) contains the listing of key/primary processes as well as the Management, Support and Customer-oriented Processes. The appendix also contains the various level 2 process documents, respective owners, and locations. These Appendixes can be found on the QOP-ISL-001 properties page in Intrepid.

The quality management system is outlined in this Quality Manual and process procedures that address specific management processes within the company. The processes are documented to the extent necessary to explain specific activities where such documentation is necessary, required by the standard, or valuable in assuring the quality of the processes, products, and services.

4.1.2 Each design center combines a responsible management structure with a defined set of process and procedures to ensure that the requirements of the customer are met in the completed design. All processes outlined in ISO9001 (Section 4 – 8) applies to the extent the requirement applies to functions or management at the design center.

4.2 Documentation

4.2.1 General

A document control system is maintained in the Quality Management System (QMS) that includes the Quality Manual, quality policy, quality objectives, reference procedures, documents, records and company policies that are required by ISO 9001, ISO/TS 16949, customer’s needs/expectations and our business needs.

4.2.2 Quality Manual

The Quality Manual is the primary document that provides a general overview of the QMS process, quality system, and quality policy. The Manual is controlled by an electronic documentation system “INTREPID”, which serves as the Retrieval Engine for Product Information and Documentation. The Quality Manual references the primary processes and procedures that are necessary to support our Quality Management Systems.

4.2.3 Document and Data Control (General)

The document control system is designed to ensure current authorized process procedures and product build instructions are available and used in all aspects of the QMS program.

Standard procedures are established for generation, revision, approval, and distribution of process procedures and build instructions. Only properly authorized, current, and controlled specifications are used in each operation performed during the manufacturing cycle or referenced by design or other support personnel.



Controlled Document

4.2.3.1(TS) Customer engineering documents are reviewed in a timely manner. Changes of internal documents to incorporate the customer special requirement are implemented using standard document control procedures.

Reference Documents:

999053	Intrepid Applications
999011	Control of Reference Standards
DOC-PROC-ALL	Document Control Procedural Specification
DOC-APPROVAL-AUTHORIZATION	Specification and Parts Approval Authorization
DOC- SPEC-ASSIGN-NUM	Specification Assignment Numbers
999017	Part Number and Structure Definition
PB1-01	Policy System
240114	Customer Documentation Review and Specification Generation Procedures

4.2.4 Quality Records

Quality records are maintained to meet ISO 9001, ISO/TS 16949 and MIL-PRF-38535 requirements, customer requirements, regulatory requirements and/or internal engineering or manufacturing needs. Quality records include but are not limited to on-line process data, product travelers, log sheets, SPC charts, attribute data, design and product release records, customer requirements review records, etc.

Site-specific procedures and/or the Record Retention Policy Bulletin define how records are identified, stored, protected, retrieved, retained, and dispositioned. The records may be retained in either paper form or in an electronic database as defined by the individual area. A retention time for each type of record is specified including start time for record retention. (Example: date of generation, date of archive, etc.)

Reference Documents:

999003	Contract Review Procedures for Sales and Marketing
999003-TS16949	TS Contract Review Procedures for Sales and Marketing
240114	Customer Documentation Review and Spec Generation Procedures
PB1-11	Corporate Record Retention Policy
880029	Wafer Fabrication Record Retention Procedure
230435	Domestic Assembly Record Retention Procedure
880027	Long Term Records Retention
501046	Probe Area Record Retention
233486	Short Term Record Retention for Shipping and QCI
235825	IQC Procedural Regulations 230108 Handling of Field Returns
230354	Reliability: Procedure for Failure Analysis
230520	IPOH Failure Analysis Laboratory
230488	Reliability: Procedure for Performing Rel Qualification Tests
235950	Receiving
236000	Analytical Services Operations
240113	Internal Quality Audit Procedures

Reference Documents: (cont)

880012	Manufacturing/Quality Training and Certification
895729	Calibration System
NPDP-XXX	Design and Product Release Review Records
NPDP-DATA-ARCHIVE-ALL	New Product Design Back Up
999053	Intrepid Applications
DOC-PROC-ALL	Document Control Procedural Specification
QAP0001	Records Control Procedure for Milpitas

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management provides evidence of its commitment to the development and implementation of the quality management systems and continually improving its effectiveness by:

- a) Establishing the quality policy and objectives. (see Sections 5.3 and 5.4)
- b) Conducting/attending management reviews. (see Section 5.6)
- c) Ensuring availability of necessary resources. (see Sections 5.5 and all of section 6.0)
- d) Communicating the importance of meeting customer's requirements, statutory (legal) requirements and regulatory requirements to the organization. (See Section 5.2 and 5.5)
- e) Giving due consideration to the risks and costs associated with continual improvement initiatives to ensure an adequate return on investment
- f) Establishing a robust system that allows top management to measure, monitor and manage the quality of the processes and products.

5.1.1 (TS) QMS process efficiency

Top management routinely reviews appropriate process efficiency information for core business objectives including but not limited to product realization and support processes. Process efficiency metrics such as on-time-delivery, manufacturing and development cycle times and efficiency is reviewed during the CEO Review.

5.2 Customer Focus

Customer satisfaction is the paramount purpose of all company activities. Meeting the requirements and value expectations of our internal and external customers is the primary task of every employee.

Top Management reviews key parameters of customer satisfaction measurements through the CEO Review process.

Reference Documents:

999019-XXX Customer Satisfaction Program

5.3 Quality Policy

5.3.1 Top management has established and periodically reviews the quality policy for suitability. The responsibility to know and uphold this policy is with every employee.

POLICY

Renesas aims to deliver customer satisfaction and enhance society by providing highly reliable and high-quality products and services.

The Company abides by the following principles in all stages of its business activities—including sales, design, development and manufacturing—in accordance with its corporate quality management system and consistent with the “Quality Policy” of the Renesas Group.

The Company will:

- Comply with all applicable legal and regulatory requirements
- Enhance product safety and trust
- Commit to continuously improve the quality of products and services
- Strive to continually improve its quality management system

Quality Policy is available on the website at the following address: [Quality Policy](#)

5.4 Planning

5.4.1 Quality Objectives Including TS 5.4.1.1

Quality Objectives are established and results monitored by Top Management. Company level data is reviewed and analyzed through department and operations meetings. Trends in performance are tracked against the objectives of the overall business plan and actions are taken as necessary for alignment.

(TS) Top Management routinely reviews quality objectives and measurement as part of the management review process.

Note: Review schedules are posted on the shared drive. The Business/Quality Alignment chart approved by top management provides an overview of the link between the vision statement, high-level business strategies, quality objectives and results.

5.4.2 Quality Management System Planning

Planning of the QMS (as evidenced by this Quality Manual) is carried out in order to meet the requirements of our customers and to satisfy our Quality Management System objectives. All functional groups at all management levels periodically formulate and deploy strategic plans. The same management levels periodically reviews the results to monitor progress to established goals. Business Reviews are conducted by top management to ensure that each of the functional groups are meeting these objectives and that improvement and corrective actions are done where objectives are not met. Management periodically reviews and measures key results with appropriate levels and functions of the organization to determine that the objectives are consistent with the quality policy and objectives are achieved. When systems change, because of continual improvement efforts and changing business needs, REA ensures that the integrity of the QMS is maintained.

Note: The overall business plan is confidential and the content is not subject to internal or external audits. The Interview process will be used to evaluate the management maintenance of the business plan and quality systems. The Leadership team maintains the review records.

Reference Document:

999074-BPR, Business Planning and Review Process Including Goal Alignment

5.5 Responsibilities, Authority, and Communication

5.5.1 Responsibility and Authority

Organization charts are maintained that show the responsibility and interrelationships within the company. Applicable procedures will also include the responsibility and authority for select activities.

5.5.1.1 (TS) All personnel who manage, perform and/or verify work are responsible for the quality of products and services provided. All such personnel are authorized to identify and record problems relating to services, products, processes, and the quality management system as a whole. All staff and personnel have the responsibility to comply with documented procedures and policies that reflect customer requirements and expectations. All personnel have the responsibility to assure that processes, in which they are working, are in a state of control and that the tasks are completed in a responsible manner. When nonconformance's are identified, the individuals that identify the problems are responsible for making the appropriate notification through designated channels and controlling further processing until the problems have been corrected. All personnel are also encouraged to initiate, recommend, or provide solutions to prevent nonconformities through designated channels.

Reference Document:

999060 Roles and Responsibilities

5.5.2 Management Representative

The representative for the ISO programs described in the scope of this document is appointed and approved by top management.

Site ISO 9001 management representatives are:

Tim Maher	NJ
John Seitters	NC (ISO 9001)
Daniel Zheng	NC (ISO/TS 16949)
Jeff Touvell	Palm Bay/Milpitas
Brannon Harris	Austin
David Hawkins	Tempe

Corporate ISO/TS 16949 management representative is:

Sunny Gupta	Milpitas
-------------	----------

The ISO/TS 16949 representative is a member of the Leadership Team with direct reporting to top management.

Irrespective of other duties, the Management Representative for the quality management system has the main responsibility and authority for facilitating the establishment, implementation, and maintenance of the quality management systems/processes and ensuring that the system continues to be compliant with the requirements of the applicable standards.

5.5.2.1(TS) The Customer representative is the applicable “Marketing” customer contact who is the expert for understanding and communication of customer expectations. Customer’s needs are cascaded throughout the organization. Each functional area has the primary responsibility to define processes that address customer requirements and product expectations.

5.5.3 Internal Communications:

The effectiveness of the quality management system processes are communicated to the various levels and functions through the use of informal and formal meetings, quality management system documentation, training, internal audits (and subsequent reporting), the corrective and preventive action systems, the document control system, and management review meetings. Further communication regarding such processes and their effectiveness is achieved through department meetings and through the management review processes.

5.6 Management Review

5.6.1 General

The CEO Review, held by top management, periodically reviews the suitability, effectiveness, and factory/new product release conformance to the quality systems and objectives described in this manual.

The Semi-Annual Sales Alignment Meeting, held by top management reviews sales status and forecast, development of key marketing and sales strategies, quality and delivery performance, and customer issues.

The Quarterly Supplier Review is held by management with primary foundries and subcontractors. Performance to established matrixes and improvement opportunities are reviewed as a minimum.

RECORDS

Management Review Records are maintained as follows:

- Management review records shall be maintained for a minimum of five years beginning with the date the record was prepared
- The disposition and maintenance of the records are as follows:
 - CEO Review records are the responsibility of Quality.
 - Quarterly Supplier Review records are the responsibility of Purchasing.
- Review records include as a minimum;
 - Attendance
 - Minutes from the meeting,
 - Relevant supporting documentation.
- Action items in the minutes shall provide the path for corrective action and follow-up.
- The review meeting records are electronic records maintained on a shared drive. Palm Bay and Tempe material suppliers are considered local and will be reviewed during their local management review process only.
- Subcontractor and Foundry metrics will be reviewed during the scheduled Quarterly Supplier Review.

5.6.2. Review Inputs are as follows:

As a minimum, the following topics will be reviewed per the schedule posted on the shared drive. Management review calendar is available on intranet site ([Finance Calendar](#)).

Inputs for reviews include but are not limited to the following:

- a) Results of customer and internal audits
- b) Customer Satisfaction Survey and Scorecard Results
- c) Process performance
- d) Product conformity
- e) Status of preventive and corrective actions
- f) Follow-up status from previous review actions items
- g) Changes that could affect the management system
- h) Recommendations for improvements of the system
- i) Analysis of actual and potential field failures and impact on quality, safety, or environment as applicable.

Note: The management review process monitors the quality objectives status and the regular reporting and evaluation of the cost of poor quality. (See 8.4.1 and 8.5.1)

5.6.3 Review Outputs are as follows:

The output of the management review includes minutes of any discussions, decisions, and actions related to any part of the process including but not limited to the following

- a) Improvements to the Quality Management System
- b) Improvements to processes
- c) Improvements to product related to customer requirements
- d) Resources needed.

Reference Document:

999074-BPR

Business Planning and Review Process Including Goal Alignment

SUB-RATING

Sub Rating

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Resource management is the responsibility of each department manager. Resources may include people, suppliers, information sources, raw materials, equipment, and infrastructure.

The design organization determines at the planning stage of each new design project the level of manpower and resources needed. These needs are incorporated into the Business Plan for the device.

6.2 Human Resources

6.2.1 General

Competency requirements for personnel are defined either in applicable procedures and/or in specific job descriptions. The individual departments are responsible for evaluation of the individual's education, skills, experience, or ability to complete a training program to accomplish the task assigned.

6.2.1 (including TS 6.2.2.1, 6.2.2.2, 6.2.2.3) Training, Awareness, and Competency

Training is a key element in the overall quality system. The system is designed to provide employees with the necessary skills and knowledge to perform task in a highly technical environment.

Training requirements have been defined for each department/function that performs work that can have an effect on the quality of the product or the QMS process. Each department or Human Resources as specified are responsible for maintaining records of the job skills including tools and techniques as appropriate, training performed and the method used to measure the trainings effectiveness. Department Managers must ensure that personnel are aware of the relevance and importance of their activities to the achievement of the quality objectives.

The department manager is responsible for determining the method for identification of skills and techniques required competency level, etc. for non-direct labor personnel. The department may elect to generate an internal document describing tools, system, operations, etc. required for a specific job or they may rely on the company level job descriptions. A performance appraisal system is utilized that clearly defines the job expectations and performance results that measure the competency level of all non-direct labor personnel. Forms and instructions on the review process are on the internal iShare site located at: Performance Management Home



Reference Documents:

880012-***	Training/Skill
895729	Calibration System
235949	Shipping/Receiving/Stockroom Training
205748	X-Ray (General spec, includes training)
230108	Field Returns (General spec, includes training)
230481	Reliability Training Procedure
235953	Purchasing Training Procedure
236000	Analytical Services (Gen spec, includes training)
240114	Contract Review (General spec, includes training)
999070-PCP	Production Control Operating Procedures (Gen. Spec, includes training)
997004	Sales Operation Training
NPDP-TRAINING	Training Document for Product Development
GEN0002	Milpitas Training Specification
Organization Charts and Job Descriptions --- Available from Human Resources for Milpitas	

Job Descriptions are controlled per Policy Bulletin PB2-22 located on the [Policies intranet site](#) or under the Human Resources intranet site ([Job Descriptions](#))

- 6.2.2.4 (TS) An environment is provided in which employees can excel and grow while maintaining personal balance. A reward and recognition system for employees who consistently demonstrate commitment, execution, innovation and extraordinary effort is in place for all employees. Policies and procedures may be reviewed on the intranet page at [Striving for Excellence](#).

6.3 (Including TS 6.3.1) Infrastructure

The Plant Services (Facilities) and IT departments provide and maintain the appropriate infrastructure necessary to achieve product realization. The infrastructure includes but is not limited to:

- Buildings, workspaces, and associated utilities are identified and appropriate flows established to maximize efficiency.
- Communication tools including but are not limited to telephone conferencing, video conferencing and lecture room projectors.
- Equipment, both hardware and software.
- All support services necessary (i.e. transport, communication).
- Electronic network with information sharing capabilities.

General Policy Bulletins, applicable Forms/Check Sheets for Plant Services/EHS, IT / PC Computing, Telecom, etc. describe the methods, responsibilities, and authorities for obtaining and managing the infrastructure. General Policy Bulletins and Downloadable Forms / Check sheets are located at: Policies and EHS Forms sites.

Reference Documents:

General Policy Bulletins

Downloadable Forms/Check sheets

Information Technology Standard Operating Procedures

GEN0003 – Milpitas Facilities Procedure



Controlled Document

6.3.2(TS) Contingency Plans

An Enterprise Risk Management Program (ERM) exists that includes risk mitigation for Manufacturing, Logistics, Orders /Sales and Information Technology. The ERM summary is documented on the following website PB3-1302: [Policies](#)

There are qualified, as applicable, alternate sources for subcontractors in the event of capacity restraints at an individual subcontractor for key products. The primary and alternate subcontractor is included in the build of material information housed in the Intrepid Build of Materials System and appropriate planning systems.

REA has a significant investment and dependency upon computer services. The Disaster Recovery plan is designed to define the alternate arrangements and document procedures so that computer operations may be quickly restored.

Foundry risk assessments are captured by foundry operations and reviewed by upper management.

Reference Documents:

Recovery\DRP Plan

(Note: The document access, maintenance and control is by IT management)

6.4 Work Environment, 6.4.1 (TS) Personnel and Product Safety, 6.4.2 (TS) Cleanliness

Facilities are maintained appropriately to achieve conformity of the product with our stated specifications. The management ensures that the appropriate human and physical factors of the work environment are considered and accommodated. Consideration of such factors includes but is not limited to health and safety conditions, work methods, handling methods, work flow efficiency, compliance to government regulations, and ambient working conditions

Reference Documents:

897XXX	Safety / EHS Specifications (as related to work environment, health and safety conditions)
880035	Wafer Fab Clean Room Procedure,
880035-Plant Services	Plant Services Clean Room Procedures
233143	Assembly Environmental Control
991XXX-994XXX	Plant Services Environmental Specs
233403	ESD Control Program
233151-A	QC Environmental Monitor-Assembly
233151-T	Environmental Control
QAP0030	Environmental Controls
GEN0003	Milpitas Facilities Procedure
EHS web site	Environmental, Health & Safety
QAP0016	Electrostatic Discharge Control
999090	Electrostatic Discharge Control Guidelines – for Engineering Labs
WWD7550	Product Storage and Logistics ISO9001
WWD7500	Manufacturing Control ISO9001
ESD	ESD Policy

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization: Including TS requirements in 7.1.1 through 7.1.4)

Information to develop a specific product may be driven from internal projections of the market needs or from specific customer needs and expectations. In the event that a customer specific expectation is incorporated in the final product design, the business unit responsible will maintain one-on-one communications with the customer to insure that the customer's needs, compliance to technical specification and acceptance criteria, are included in all phases of the product realization process. Planning starts with the preparation of a Business Plan for each primary circuit design. The applicable New Product Development Process Procedure (NPDP) defines the activities included in the business planning and product realization processes.

The Business Plan outlines are defined in the procedures and the applicable check sheets / forms utilized by the appropriate group. As appropriate, the Business Plans address the resources needed, the expected time schedules, the projected cost of development, the expected costs in manufacturing and any special equipment or process requirements.

In planning product realization, the organization determines

- a) The quality objectives for each released product:
 - To meet the requirements of the proposed specification/data sheet.
 - To meet the Qualification Plan as defined by Reliability and Qualification Engineering Groups.
 - To meet the schedules as defined in the business plan.
 - To meet the cost projections as defined in the business plan.
 - To meet customer technical specifications in the event the product was designed for a unique customer.
 - Details of customer specific design and development projects are considered priority between the customer and REA.
- b) The processes, documentation, and resources specific to the product.
- c) The design process and documentation requirements are defined in the NPDP series of process procedures and are not product specific. Resources specific to the product are defined in the business plan.
- d) The required verifications, validation, monitors, specific to the product and criteria for acceptance are defined. The testing required and the criteria for acceptance are based on the final product datasheet for the device. The actual types of test for verification and validation are determined and agreed to by the development team.
- e) Records are needed to provide evidence that the realization processes and resulting product meet requirements. The evidence of meeting requirements is the Characterization Data report, the results of the Qualification Plan, and the final cost data.
- f) A formal product release process referred to as "Redline Release" is utilized. The release process includes verification of such items as specific data for acceptance, approval of the qualification plan, etc.

Reference Documents:

201-200-000001	Device Redline Approval Loop
201-200-000000	Redline Procedure Specification
NPDP-GENERAL	New Product Development Procedure
230415	Reliability Qualification Requirements
WWD7332	Reliability Guideline_ISO9001
999069-NPP	New Product Proposal Process
230482	Reliability Stress Lab Scope

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

- a) Regional Marketing and Sales groups provide price quotes for products upon request for customers and potential customers.
- b) All customer requirements that do not conform to the standard data sheet requirements and terms and condition warranty are sent to Customer Engineering for review and resolution of special requirements. The review of customer requirements includes a review of any regulatory requirements related to the product (e.g. import/export criteria), standard pack material etc.
- c) During new product development, customer product specific requirements such as parameters, technical inputs, application ideas or special device packaging requirements are incorporated into the appropriate specifications and data sheets as negotiated.

7.2.1.1 (TS) Customer Designated Special Characteristics

In the event a customer specific design was developed; customer special characteristic would be designated, documented, and controlled throughout the design and development process.

7.2.2 Review of Requirements Related to the Product

- a) Orders are reviewed and entered by appropriate Sales personnel.
- b) When a request exceeds standard procedures and requirements, a review of the request is made prior to accepting the order. Any difference that exceeds standard capabilities and the customer's requirements are resolved before the order is accepted and processed.
- c) Accepted special requirements are documented and tracked by using unique part number reference in the ordering system
- d) When order requirements change, REA or representatives of REA ensure that relevant documents are reviewed and updated.
- e) Records of the requirements review and approval are maintained.

7.2.2.1(TS) Systematic reviews and approval are completed as defined in the individual design and development specifications.

7.2.2.2(TS) Manufacturing feasibility is evaluated during the identification phase and verified throughout the design and development flow. Risk analysis are completed and documented for customer specific requirements and TS16949 designated designs.



7.2.3 Customer Communications

REA has determined and implemented effective arrangements to ensure good customer communications in relation to:

- a) Requests for product information, technical issues, specification, etc.
- b) Inquiries, contracts or order handling or status, including amendments.
- c) Customer feedback, including customer complaints.
- d) A customer “hotline” is maintained to receive customer comments and is available 24 hours a day. (1-888-INTERSI – 1-888-468-3774)

7.2.3.1(TS) Customer specific requirements are identified and agreed to during the contract review and contract acceptances process. Additional systems and format requirements are implemented in compliance to the agreed to contract.

Reference Documents:

999003	Contract Review Procedures for Sales and Marketing
999003-XXX	TS Contract Review Procedures for Sales and Marketing
999010	Customer Service Training and Website Control
240114	Customer Documentation Review and Spec Generation
997005	PPP Order Entry Process Management
999019-XXX	Customer Satisfaction Program

7.3 Design and Development

7.3.1 Design and Development Planning (Including 7.3.1.1 TS). The organization plans and controls the design and development of the product by assigning a multidisciplinary team to every project and applying a set of defined procedures (reference the applicable NPDP series specifications for additional details).

- 7.3.2.1 Design and Development Inputs (Including 7.3.2.1 (TS))
The processes include prescribed inputs to functional and performance requirements, applicable information derived from similar designs, design rules, applicable targeted customers, etc. Business plans are generated and approved for each design project. The business plan includes information such as targets for timing, costs, product grade, etc.
All subcontractors for design and development will follow the applicable NPDP-XXX or NPDP-GENERAL procedures as are used for internal design.
- 999069-NPP – competitor analysis, information from previous designs, cost and timing targets (in the product Business Plan)
 - NPDP-GENERAL – functional and performance requirements and internal inputs(datasheet, engineering specs), customer requirements, targets for quality and reliability, special characteristics (see Quality Plans), supplier feedback
 - 999065-APQP – other product design inputs
 - 999064-DFMEA – information from previous designs
- 7.3.2.2(TS) Manufacturing Process Design Inputs
Except for the Palm Bay building 59 fabrication facility, manufacturing processes are subcontracted. Manufacturing subcontractors are required to be ISO/TS 16949 certified. As a registered ISO/TS 16949 company the subcontractor is responsible for the process design activity.
The following process specifications address the specific manufacturing process design inputs:
- NPDP-GENERAL – product design output data (see process flow), target for process capability.
 - 999069-NPP – target for cost, customer requirements
 - 999064-DFMEA – experience from previous developments
- 7.3.2.3(TS) Special Characteristics
Product specific control Plans, and FMEA's, will be generated and special characteristics documented for product designed for compliance to ISO/TS 16949

7.3.3 /7.3.3.1(TS) Design and Development Outputs.

The output of the design project defines the physical layout of the device and a bill of Material (BOM) defines the construction and testing requirements. Samples of the product are built and tested to verify that the input requirements are met. Testing includes electrical testing to verify the data sheet requirements, qualification testing to verify reliability and application testing to validate performance in the intended application.

Product designed for targeted ISO/TS 16949 customer applications will also have FMEA forms completed and on file and applicable special characteristics identified. Product error proofing methods are used as applicable.

Design and development outputs for the TS 16949 requirements are included in the following specifications.

- 999064-DFMEA
- NPDP GENERAL
- 999065-APQP

7.3.3.2 (TS) Manufacturing Process Design Output

Manufacturing subcontractors are required to be ISO/TS 16949 certified. As a registered ISO/TS 16949 company the subcontractor is responsible for their process design activity.

Specific manufacturing design outputs for TS 16949 requirements are included in the following:

- 999065-APQP Checklist for Phase 3 (Process Design and Development) shows specifications and drawings, FMEA, Control Plan, Process Flows, Work Instructions
- NPDP-GENERAL Addresses process approval criteria (PPAP), methods for rapid detection and feedback of non-conformities through the product control plan and data for quality, reliability and measurability
- 999064-DFMEA Results of error proofing activities

7.3.4 Design and Development Review

A series of gates are identified in the applicable design related document. Gates are used to review progress and are held at prescribed intervals to evaluate the ability of the results of the design to meet requirements and to identify problems and propose necessary actions.

7.3.4.1(TS) Monitoring

Measurements at specified stages of design and development are defined, analyzed and reported with summary results as an input to management review. Gates are identified at select points in the process as identified in the NPDP specification.

Note: These measurements include quality risks, costs, lead-times, critical paths and others as appropriate.

7.3.5 Design Verification

During the design phase, various tools are used to verify that the design meets the input requirements. In-process checks may include as applicable: Circuit Simulation checks functionality of the design, Design Rule Checking (DRC) ensures that the design rules are met, and Layout vs. Schematic checks that the layout and the schematic match.

Prototype samples are manufactured and tested to the test program that represents the datasheet specifications and acceptance criteria. Specific data and records are defined in the applicable NPDP-XXX procedures and/or in the business plan.

Samples are subjected to stress and reliability testing according to specification 230488, WWD7332, 230415 and any additional requirements specified by the datasheet, customer, or determined by the team.

Data and records identified as “Quality Records” are maintained as prescribed by the applicable NPDP-XXX, 230XXX, or other applicable internal procedures that are related to the verification process.

7.3.6 Design Validation

Design validation includes demonstrating manufacturability to minimum yields and the successful completion of reliability qualifications. The product is designed released using the redline release procedure defined in the 201-200-000000 procedure.

7.3.6.1, 7.3.6.2, 7.3.6.3(TS) Customer Specific Product Requirement

Product designs are intended for standard applications. ISO/TS 16949 systems are followed as applicable when a design is targeted for customers that require ISO/TS requirements. However, the product design operating characteristics are typically not custom for a specific customers requirements.

7.3.7 Design Changes

Any changes to the design deemed necessary because of the verification and validation procedures are identified, documented, reviewed, and approved by authorized personnel. Records of the change will be documented. Any changes implemented after design release will be evaluated for potential impact to product in process, in stock, or at the customers. The changes will also be evaluated for customer notification requirements.

Reference Documents:

201-200-000000	Redline Procedures
230415	Reliability Qualification Specification
WWD7332	Reliability Guideline
230488	Reliability Procedures for Performing Rel Testing
Device Specification	Product Specific Datasheets
225XXX	Design Rules
999004-XXX	Change Notification Policy and Procedures
NPDP-GENERAL	New Product Development Procedure
999064-DFMEA	(TS) Design Failure Mode and Effects Analysis
999065-APQP	(TS) Advanced Product Quality Planning Process
999063-PPAP	(TS) Production Part Approval Process
999056-XXX	Process Change Review Board (PCRB) PAT

7.4 Purchasing

7.4.1 Purchasing Process

- a) Engineering, Purchasing, Manufacturing, and Subcontractor Teams establish and maintain systems to purchase production material and manufacturing services.
- b) Suppliers are selected based on their ability to meet quality and service requirements, their commitment to continuous improvement, and cost competitiveness. The selection is based on parts/production line qualification, review of the supplier's demonstrated capability and performance, and quotation analysis.
- c) Materials and services that can have an effect on the quality of the product will be purchased from subcontractors/vendors/suppliers that are approved.



7.4.1.1 & 7.4.1.2 & 7.4.1.3 (TS)

Purchased product and material is the responsibility of the subcontractor. It is a requirement that subcontractors be ISO/TS 16949 certified. Material requirements, as applicable, are identified and are required to be compliant to all customer and applicable regulatory requirements.

Reference Documents:

SUB-I-QUAL-SUBCON-LIST	Subcontractor Qualified List
SUB-I-APPROVAL	General Procedure for Subcontractor Approval
PUR-MAN-001	Purchasing Functional Manual
896729	Calibration Survey Procedures
235823	Supplier Qualification Procedures
235825	IQC Procedural Regulations
QAP0018	Approved Supplier / Subcontractor List
SUB-RATING	Sub Rating

7.4.2 **Purchasing Information**

- a) Purchasing orders are issued in accordance with the Purchasing Functional Manual
- b) The purchasing of any raw material requires an approved Purchasing Order for all material utilized in the production of product. The materials specification number, revision level, quantity, and delivery schedule are clearly stated on the Purchase Order.
- c) The design centers do not directly manufacture product and the purchase of materials does not apply to these facility.
- d) Baselines are issued to all suppliers classified as “subcontractors” for die foundry, and subcontractor services (assembly/test/tape and reel, etc.) that define in detail the process conditions and product requirements agreed to including material sets for assembly subcontractor services. Qualified subcontractors are responsible for the review and approval of material purchased for REA product.
- e) Purchasing requirements may extend to include (where applicable) the Quality Systems requirements. These requirements may be stated in the purchase order, purchase baseline/procurement document or in the contract.

Reference Documents:

PUR-MAN-001	Purchasing Functional Manual
-------------	------------------------------

7.4.2 Verification of Purchased Product/Services

General

Management considers the amount of control exercised at the subcontractor's premises, product history of quality, the impact to production and end customers, etc. when establishing the level of verification required.

Materials

Design and development centers do not manufacture any production product.

Production Operations are applicable to the Palm Bay facility. Procurement documents afford REA the right to perform source inspection on raw material to verify production materials meet specified requirements. A review of the supplier product parameter data and process control data are also methods used to monitor the product compliance to specified requirements. IQC has the responsibility for verifying quality conformance and the authority to form teams to disposition discrepant material and request corrective action.

Subcontracted Product Services (foundry, assembly, test, etc.)

Subcontractors operate to strict baselines that include a detailed monitor program to assure the quality of the product is maintained. Routine critical subcontractor audits are conducted to verify that compliance to the baseline process conditions are implemented and controlled. The validation and control of suppliers of materials for the subcontracted manufacture of products are the responsibility of the subcontractors.

Subcontracted Calibration Services

Calibration services are procured from an accredited laboratory. Internal procedures define verification requirements of critical parameters and conditions.



7.4.2.1 & 7.4.3.2 (TS)

It is a requirement that the subcontractors of wafer fabrication, manufacturing, and testing, operations to be ISO/TS16949 certified. As such the individual subcontractor is responsible for the incoming product quality and supplier monitor for purchased material. The subcontractors are monitored by conducting subcontractor audits that include ISO/TS 16949 systems requirements.

Reference Documents:

SUB-I-QUAL-SUBCON-LIST	Qualified Subcontractor List
PUR-MAN-001	Purchasing Functional Manual
449 -XXX-XX -X	Sub-Contractor Baseline Documents
SUB-XXX-XXX	Foundry/Subcontractor Requirements Series Documents
SUB-I-XXX	Internal Documents Related to Foundry/ Subcontractor Services
235825	Incoming Quality Control Procedural Regulations
240113-SUPPLIER	Material Supplier Audit Procedure
OUT-PROC	Foundry/Buy Resale Purchase Document Template
40P-925-CAL-PROC	Development Center Calibration Procedure
WWD7630	Laboratory Standard ISO9001
896729	Calibration Survey Procedures
QAP0018	Approved Supplier / Subcontractor List

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

REA does not enter into any service contracts with the end customer. However, does support the customers in product application needs and the resolution of any product concerns or issues.

Product controls for subcontractors are governed by baseline and other requirements documents that follow the best practices as identified below.

7.5.1.a General Controls

Documented work instructions and product flows include requirements for in-process and final inspections, and applicable statistical process control monitors. All team members, support personnel, and management has the responsibility to ensure these inspections/tests are carried out as specified.

-
- 7.5.1.b Production Related Controls / Material Controls (Applicable to the Palm Bay Manufacturing)
- a) All critical raw materials are required to conform to material specifications established by Engineering. Incoming Quality Control verifies conformance through inspection or review of supplier-provided data (e.g., Certificate of Analysis/Conformance), as required. Released material is moved to stock.
 - b) Non-conforming material is identified and placed on hold pending Material Review Board (MRB) disposition. The supplier shall be obligated to provide a corrective action response for rejected material at the MRB's direction.
 - c) Material urgently needed for production may be released without prior IQC inspection using the Early Release procedure. Such material is at risk pending the results of the IQC inspection.
- 7.5.1.c Production Controls/Inspections (Applicable to the Palm Bay Facility)
- a) Manufacturing operations are controlled to ensure applicable internal and external customer-required standards of quality are met or exceeded. In-process and final inspection procedures are identified in the process flow and are defined in internal operating specifications for each manufacturing area. Sampling plans and acceptance criteria are established for all inspection and testing activities used both internally and by subcontractors. All team members, support personnel, and management have the responsibility and authority to ensure product is processed to specified requirements in accordance with the quality standards and documented procedures.
 - b) All operations required to fabricate, assemble, test and monitor product have appropriate work instructions and designated flows that define process and inspection requirements. These work instructions include, where appropriate, samples, drawings, and detailed operational instructions to ensure quality levels are maintained. All applicable personnel are jointly responsible for ensuring the current work instructions are available.
 - c) Final electrical testing is performed according to the applicable process flow for each product. Test parameters and conditions are contained in the test program. Test programs for subcontractor and internal use are generated, approved, and controlled by the applicable product-engineering group.
 - d) Software control is the responsibility of the department who manages, administers, and/or uses the software. Procedures used to govern critical software are documented in internal process specifications, Policy Bulletins, or other controlled and approved documents.
 - e) Production is carried out under environmentally controlled conditions as specified in internal documentation.
 - f) Preventive maintenance schedules and procedures are followed to ensure continued suitability of equipment.
 - g) Critical process and product characteristics are identified and monitored at selected points in the production process. Data may be recorded in the electronic Factory Control System, on SPC charts, lot travelers, or appropriate logs.
 - h) Tools such as Design of Experiments (DOX) and other statistical methods are used to evaluate new and existing processes and products. Critical equipment and processes are qualified for production prior to use.



Controlled Document

7.5.1.1(TS) Control Plans, 7.5.1.2 Work Instructions 7.5.1.3 Verification of Job Set-Up's, 7.5.1.4 Preventive and Predictive Maintenance, 7.5.1.5 Management of Production Tooling
Except for the Palm Bay building 59 fabrication facility, the manufacturing and testing of product for ISO/TS 16949 applications is the responsibility of the selected subcontractor for foundry, assembly, test, and shipping operations. The contracted companies are required to be ISO/TS 16949 certified. eriodic audits are conducted along with the compilation of supplier rating reviews on a periodic basis to validate compliant and effective production systems.

7.5.1.6 (TS) Production Scheduling
A comprehensive planning system is used to review and approve customer purchase orders for scheduling requirements. The system includes methods to communicate the requirements to the respective subcontractors and monitor the status throughout production.

7.5.1.7 (TS) Feedback of Information from Service, 7.5.1.8 Service Agreement with Customer
REA does not engage in any service agreement contracts but does service the customers' needs and expectations for product application and problem resolutions. REA also incorporates any customer special services or product requirements into a part specific application and generates a standard process flow to accommodate the customer needs and special requirements. Product processed through the assigned flow is then considered standard for that application and customer needs.

Reference Documents:

235825	Incoming Quality Control Procedures
206XXX	DV Line Travelers
352XXX	Assembly Travelers
420XXX/437XXX	Fab 4&6 Inch Flows/Travelers
54XXX	QCI Travelers
55XXX	QCI Travelers
87XXX	QCI Travelers
9QXXX	QCI Travelers
210772-XXX	Die Foundry Requirements and Controls
210815-XXX	Buy/Resale Requirements and Controls
210834-XXX	Assembly Subcontractor Requirements and Controls
449-XXX-XXX	Assembly Baseline Documents
SUB-XXX-XXX	Applicable Subcontractor Control Documents
Reference Documents for production scheduling	
999041	Warehouse System
999041-OTD	OTD Measurements Automotive Direct Ship
999041-PDC-DISTCENT	PDC Ware House List
999043-DEL	Product Delivery Policy
999070-PCP	Production Control Operating Procedures

Note: The following series of specifications define the test programs to be used, pack requirements by package style including tape and reel, label requirements, and part marking for both internal and subcontractor use. TSTF, PKSP, BARD, and BRLD/BRSP

7.5.2. Validation of Processes for Production and Service Provisions
REA does not engage in any service agreement contracts but does service the customers' needs and expectations for product application and problem resolutions. REA qualifies all process for production and incorporates any customer special services or product requirements into a part specific application and generates a standard process flow to accommodate the customer needs and special requirements. Product processed through the assigned flow is considered standard for that application and customer needs.

Reference Documents

230354	Reliability Procedures for Failure Analysis
230520	IPOH Failure Analysis Laboratory

7.5.3 Identification and Traceability:

7.5.3.1 General

The product identification and traceability system provides the means to capture manufacturing information and associate it with finished product. Product identification and traceability requirements are detailed in internal process procedures. The product nomenclature code structure is defined in the electronic data system. Internal and external manufacturing is responsible for maintaining lot identification and traceability throughout the manufacturing flow. When required by contract, full traceability is provided from the finished product back to the critical raw materials used.

7.5.3.2 Identification

Unique lot numbers are assigned for all production and development lots both internally and by the applicable subcontractor.

7.5.3.3 Traceability

The lot traveler and/or electronic record is the primary basis for traceability. The record details the history of the lot through the production cycle.

Key attributes are identified and captured in a database on all lots. The lot history data is readily retrievable by using the database referred to as Quick Trace and or through the subcontractor tracking system from the wafer fabrication lot through final product shipment.

Reference Documents:

999017	Part Number and Structure Definitions
999044	IT Traceability Requirements
SUB-LOT-COMBINATION	Subcontractor Lot Combination Procedure
SUB-DATE-TRACECODE	Subcontractor Date-Trace Code Procedure
235825	Incoming Quality Control Procedures

7.5.4 Customer Property and Customer Production Tools
REA currently has no customer owned equipment or customer owned inventory. In the event that customer engagements would require the use of customer owned equipment or customer owned inventory, the same systems used internally for process control, asset tracking, applicable calibration, etc. would be utilized.

7.5.5 Preservation of Product
General
Procedures have been implemented for all materials and products under REA's control. Material/product are stored and handled in such a way as to preserve conformity of the product. Such protection is also extended to product being delivered, which is packaged appropriately to preserve conformity during delivery.

Handling, Storage, and Preservation

- a) Handling of material/product at various process steps is defined in the specific support document unique to the area.
- b) An ESD program has been developed that defines approved material, workstation grounding, and handling requirements to prevent degradation of device performance.
- c) Clean room standards have been developed to minimize product contamination during processing.
- d) Temperature and humidity limits are defined for critical process and storage areas and are monitored accordingly.
- e) Noncompliant product is removed from the process, labeled as rejects and segregated to scrap locations.

Packing and Delivery

Finished goods are packed in approved antistatic containers. The detailed packing and labeling requirements are defined in the internal final pack specification and the applicable Brand Pack Specification drawing. Product for delivery is packed in designated containers adding appropriate dunnage to prevent movement within the containers to avoid damage to the product during shipment.



7.5.5.1(TS) Storage and Inventory

Shelf life is identified for all products and key materials in stock. In the event that the shelf life is exceeded the material would be scrapped or reviewed by a material review board for actions to validate product or material conformance.

Reference Documents:

233403	ESD Control Program
510700-002	Pack/Ship Procedures (Bldg. 58)
233151-T, A	QA Environmental Monitor
501043	Probe Pack and Ship Procedures
880001	Product Handling (Post Seal)
880020	Assembly Product Handling
233143	Assembly Clean Room Specification
880035	Fab Clean Room Specification
990032	Plant Services Corrective and Preventive Action
449-XXX	Baseline Documents for Subcontractor Services
210772-XXX	Purchase/Baseline Requirements for Die/Wafer Purchases
210815-XXX	Purchase/Baseline Requirements for Buy/Resale Purchases
235833	Environmental Control Procedures for Material Storage
510704	Dry Pack Procedures
SUB-GENERAL	General Quality and Reliability Requirements for Subcontractors
MPX0048	End of Line Packing
MPX0112	Pack Tape and Reel Procedures
QAP0076	Milpitas Receiving
QAP0077	Milpitas Shipping Specification
QAP0016	Electrostatic Discharge Control
QAP0030	Environmental Controls
WWD1400	Environmental Management System
FG - BPC	Product Specific Brand Pack Card
999041	Warehouse Systems

7.6 Control of Monitoring and Measuring Devices

- a) Equipment used to determine the conformance of product is identified with a unique equipment number, tracked, and calibrated at regular intervals. Site-specific written procedures outline the overall system and define requirements for specific equipment calibrations. All calibrations are either performed by internally or by an approved commercial/independent contractor.
- b) REA does not currently have any government or customer owned equipment. In the event that government or customer owned equipment was supplied, REA would use the same system for monitoring, tracking, calibration, etc. as used to control REA owned equipment.
- c) Equipment is clearly labeled as to its calibration status, calibration due date, and the responsible calibration personnel. A recall system provides advanced notification for equipment due for calibrations as well as overdue notices. Out-of-Tolerance (OOT) events are documented and affected product is identified and dispositioned accordingly.
- d) Equipment is calibrated at periodic intervals that are determined on the basis of manufacturer recommendation, historical data, and/or statistical studies. Equipment is calibrated against certified standards traceable to nationally recognized standards. (N.I.S.T.) When standards do not exist or national traceability is not feasible, the basis for calibration shall be defined by internal procedures.

7.6.1(TS) Measurement Systems Analysis, 7.6.2 Calibration/Verification Records

All subcontractors and foundries are required to be certified to ISO/TS 16949. The subcontractors are responsible for the control of measurement systems identified in the control plan. For internal wafer fabrication processes, REA is compliant to ISO/TS 16949 in the control of measurement systems identified in the control plan per specification 999071-MSA.

Calibration records are identified and maintained in accordance with industry standards that include the records stated in the ISO/TS16949 standard.



7.6.3(TS) Laboratory Requirements: ISO17025 Certified external laboratories calibrate equipment used for the qualification and failure analysis of product.

Calibration systems used for the outsourced production measurement and monitor requirements are the responsibility of the subcontractors that are required to be certified to the standard.

Reference Documents:

895729	Calibration System
896729	Calibration Survey Procedures
40P-925-CAL-PROC	Development Center Calibration Procedure
40R-925-EAGLE-CAL	Eagle Test System Maintenance-NC
40P-925-EAGLE-CAL	Eagle Test System Maintenance-NJ
WWD7630	Laboratory Standard ISO9001
ANSI/NCSL Z540	Calibration Laboratories and Measuring and Test Equipment
ISO Guide 17025	General Requirements for the Competence of Testing and Calibration Laboratories
QAP0003	Calibration and Control of Test & Measuring Equipment (Milpitas)
999071-MSA	Measurement System Analysis Procedures
230354	Reliability Procedures for Failure Analysis
230520	IPOH Failure Analysis Laboratory
230XXX	Reliability Lab Specifications

8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General

Monitoring and analysis systems are planned and implemented to demonstrate the conformity of the product and to ensure the conformity and effectiveness of the quality management system.

The process is monitored and product is tested to the full requirements of the specifications. Data is analyzed using statistical and other techniques to guarantee conformity to process and product requirements.

Management and/or appropriate team members routinely review the quality management systems for improvement opportunities and to evaluate the effectiveness of the quality management system.

8.1.1, 8.1.2(TS) Statistical Tools and Concepts

REA's practice is to identify tools, processes, control plan items etc that would benefit from SPC. Appropriate training is provided to all personnel required to implement and generate SPC systems.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Periodic surveys are conducted of key customers to solicit information regarding the customers' level of satisfaction or dissatisfaction with products or customer support systems. A team evaluates the results of the survey, in conjunction with customer scorecards, for continual improvement opportunities.

8.2.1.1 (TS) Specific data and measurements are documented for customer satisfaction and will be reviewed as defined for customers purchasing product compliant to ISO/TS 16949 as a minimum.

Reference Documents:

999019-XXX

Customer Satisfaction Program

8.2.2 Audits, 8.2.2.1(TS) (Management Review Audit)

Internal Audits (including Management review audits)

Internal audits, which are planned and scheduled, are used to validate that our quality management system and process has been implemented and maintained. These audits determine whether the quality management system conforms to the planned and documented arrangements including the requirements of ISO 9001, ISO/TS16949 and where applicable to MIL-PRF-38535.

Internal auditors are assigned the task of conducting and administration of the internal audit function. Auditors trained and certified in audit disciplines, ISO 9001 Standards, ISO/TS 16949 standards, where applicable MIL-PRF-38535 Standards, customer specific requirements, and area process specification interpretations, perform all audits. The audit team is independent of the area audited.

When deviations are identified during the audit process, responsible parties address these deviations with root cause analysis and corrective and/or preventive action activities. Managers responsible for the area being audited are responsible for taking timely actions in response to the audit finding.

The quality audit administrator and audit team are responsible for follow-up audits on all responses to ensure overall effectiveness of the corrective/preventive action and continuous improvement plans.

8.2.2.2 (TS) Manufacturing Process Audits

All outsourced subcontractor/foundry manufacturing process audits are the responsibility of the subcontractors/foundries that are required to be compliant to ISO/TS16949 for internal manufacturing process audits. Audits are performed for all subcontractors and foundries for compliance to systems and production process requirements in accordance with the documented annual schedule. Audits are conducted to determine compliance to systems and production process requirements for applicable ISO and ISO/TS 16949 clauses.

8.2.2.3 (TS) Product Audits

Products are audited at defined intervals to prescribed criteria. The audit is conducted by the designated operations facility responsible for the activity. Results are reported on a routine basis.

8.2.2.4(TS) Audit Plans

The standard internal audit plan is developed yearly and includes all quality management related processes including applicable lab and production operations. ISO/TS 16949 management processes will be audited for all applicable quality management process and shifts on yearly basis.

Subcontractors and Foundries are required to be ISO/TS 16949 certified and manage the internal audit plan for production processes performed.

8.2.2.5(TS) Internal Auditor Qualification

Standard practice is for auditors to be trained and certified to the standards and disciplines assigned for audit.

Reference Documents:

240113	Internal Quality Audits (Palm Bay)
240113-001	Quality Audit Checklist (Palm Bay)
SUB-GENERAL	General Operating Requirements for Subcontractors

8.2.3 Monitoring And Measurement of Processes

Monitors/metrics for processes that may affect the Quality Management System are established and results reviewed. When planned results are not achieved, the organization collecting the measurements takes action to ensure conformity.

Software control is the responsibility of the department who manages, administers, and/or uses the software. Procedures used to govern critical software are documented in internal process specifications.

Production is carried out under environmentally controlled conditions as specified in internal documentation to ensure processing and testing conditions are repeatable.

Preventive maintenance, environmental conditions, and critical process and product characteristics are identified and monitored at selected points in the production process both internally and at the subcontractors. Data may be recorded in the electronic Factory Control System, on SPC charts, lot travelers, or appropriate logs. The data is routinely reviewed for repeatability and reproducibility of the process and resulting product.

Tools such as Design of Experiments (DOX) and other statistical methods are used to evaluate new and existing processes and products. Critical equipment and processes are qualified for production prior to use.

The competency level of all personnel performing tasks that could impact the overall management systems are routinely reviewed for competency and affectivity in achieving goals and objectives that support the overall management system.

8.2.3.1(TS) Monitoring and Measurement of Manufacturing Process

ISO/TS 16949 products are manufactured and tested by subcontractors that are certified to the standard. In addition to the subcontractor's third party certification, subcontractors are audited for compliance and effectiveness on a periodic basis. ISO/TS 16949 products manufactured at Palm Bay, building 59 fabrication facility are audited to the applicable clauses in the standard.

8.2.4 Monitoring and Measurement of Product

All critical raw materials are required to conform to material specifications established by Engineering. Incoming Quality Control verifies conformance through inspection or review of supplier-provided data (e.g., Certificate of Analysis/Conformance), as required.

REA maintains internal documented work instructions and product flows that include requirements for in-process /final inspections, and statistical process control monitors. All team members, support personnel, and management has the responsibility to ensure these inspections/tests are carried out as specified. Specially trained and certified technologists carry out inspection and testing activities.

Inspection and test requirements, conducted by a subcontracted services organization, for the assembly and test processes are clearly defined in the appropriate baseline and/or flow which is mutually agreed to by the subcontractor.

Final test results are routinely reviewed by product engineering. Product that falls below expected results are evaluated/analyzed prior to shipment. Corrective action is initiated as appropriate.

Test results are captured in the electronic WIP tracking system and/or on Final test travelers. No product is shipped until all associated inspections and tests have been satisfactorily completed.

During design and development process, the product developed is extensively tested as part of the validation and verification process (see 7.3.5, 7.3.6) before the product is released to production. Records in the form of data on the characterization tests, the yield and the reliability tests are studied and approved before the device is signed off to production.

Reference Documents:

TSTF XXX	Product Specific Test Flows
TSTP	Product Specific Test Programs
SUB-XXX-XXX	Series Specifications for Subcontractor Control

8.2.4.1(TS) Layout Inspections and Functional Inspections

Lay out inspections and functional testing verification are included as part of the product release procedure. Established process control and testing validate the product remains compliant to the original design and dimensions.

8.2.4.2 (TS) Appearance Items

Appearance items as referred to in the standard do not apply.

8.3 Control of Nonconforming Product

Procedures have been established and maintained to ensure that product that does not conform or is suspected of not conforming to specified requirements, unidentified product or material, is prevented from unintended use. Systems are established both internally and at the subcontractors that provide for the identification, documentation, evaluation, segregation, (when practical) and disposition of nonconforming product. Containment, rework/rescreen to specified procedures, and corrective action requirements are determined by the Material Review Board and implemented accordingly. Customers are promptly notified in the event a containment investigation identified product that had been shipped.

Product, identified internally as noncompliant to established requirements, is not shipped unless written customer approval is received.

In the event that nonconforming material is observed and reported by customers, formal corrective actions will be solicited from responsible areas.

Note: 8.3.1 to 8.3.4 (TS) requirements are included above.

Reference Documents:

999059	Ship Hold Procedure
999013	Product Recall and Alert Procedure
QAP0088	MRB Material Review Board
SUB-CORRECTIVE-ACTION	Corrective Action System
999067	Waiver Procedures
999091	Quicktrace Lot Quarantine Procedure
WWD8300	Control of Non-conforming product

8.4 Analysis of Data

The organization collects and evaluates 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 made.

Data analyzed includes but is not limited to the following:

- a) Product Test Data and Product Conformance Data
- b) Process monitoring data
- c) Data from the Manufacturing Suppliers
- d) Customer Satisfaction Data Where Applicable

8.4.1(TS) Analysis and Use of Data

Data is reviewed and trends compared with progress towards objectives including but not limited to objectives identified in section 5.3.2. As applicable, data is compared to competitors or industry benchmarks.

8.5 Improvements

8.5.1/8.5.1.1 (TS)

Continual Improvement

The organization continually improves the effectiveness of the quality management systems and the resulting product through the deployment of the quality policy, quality objective, review of audit results (from both internal and external resources) analysis of product, process control, customer satisfaction data and other applicable sources of information.

REA is dedicated to the practice of continual improvement in every aspect of our business objective.

8.5.1.2(TS) Manufacturing Process Improvements

ISO/TS 16949 products are manufactured by subcontractors certified to the standard. The continual improvement of outsourced operations is the responsibility of the certified subcontractor. REA is responsible for the continual improvement of the Palm Bay building 59 fabrication processes.

8.5.2 Corrective Action System

The quality system provides an effective corrective action program that takes actions to eliminate the cause of the nonconformity in order to prevent recurrence. The extent of the corrective action is commensurate with the type of problem encountered.

Analysis of discrepant material or process data, internal/ external customer feedback, and/or individual's recognition of an ongoing problem may result in a corrective action request and subsequent corrective action resolution. Causes are determined, actions are taken, and records are kept per internal documented procedures. The industry 8D process is used for the evaluation and implementation of a corrective action activity.

Note: ISO/TS 16949 Para 8.5.2.1 Problem, 8.5.2.2 Error-Proofing, 8.5.2.3 Corrective Action Impact, and 8.5.2.4 Reject Product Test/Analysis requirements are included in the general description of the corrective action system that is used for all applications.

Reference Documents:

SUB-CORRECTIVE-ACTION	Corrective Action Systems
230108	Handling of Field Returns
880032	Internal Corrective and Preventive Action Procedures
230354	Failure Analysis Procedures
230520	IPOH Failure Analysis Laboratory
WWD8520	Corrective Preventive Action



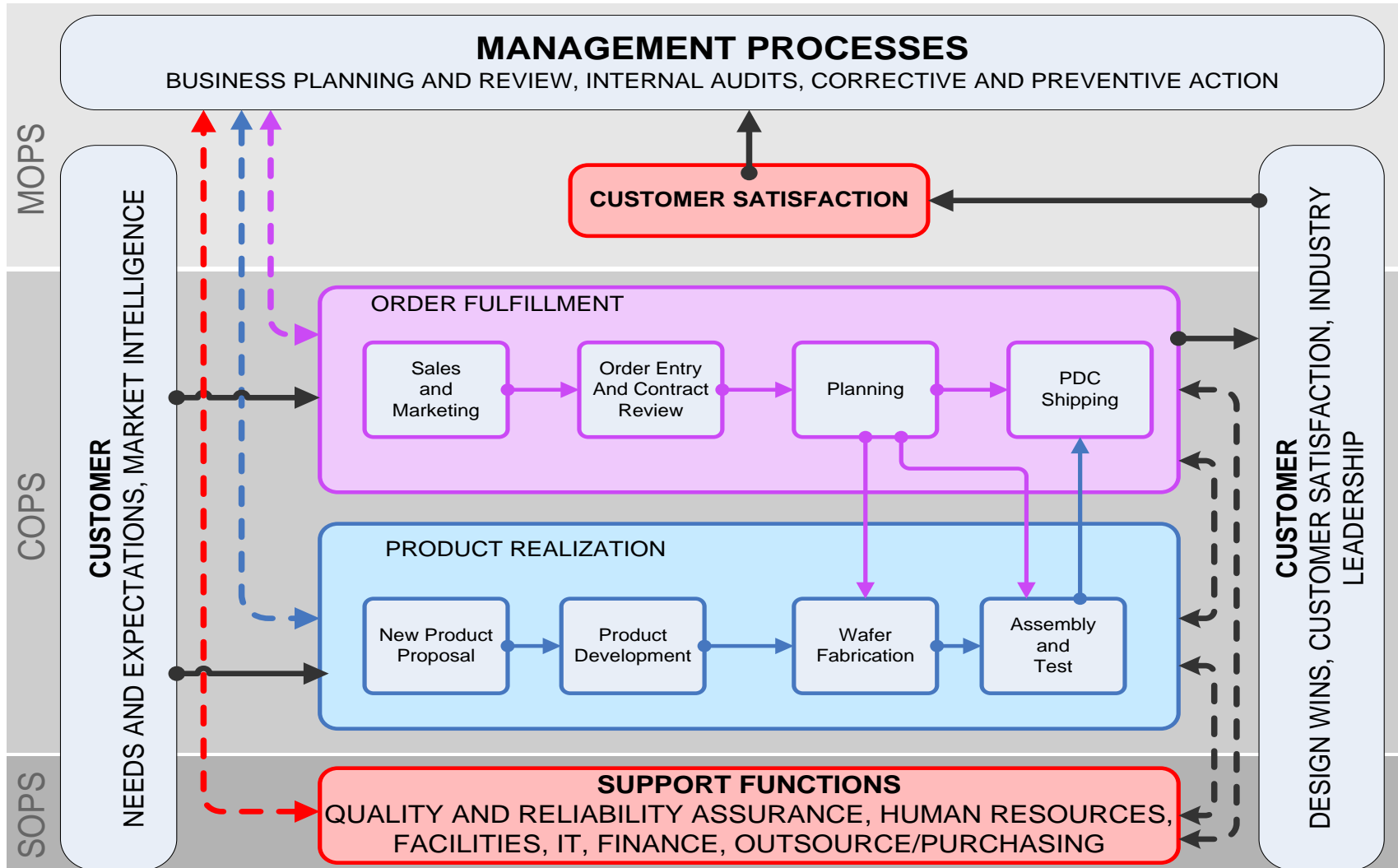
8.5.3 Preventive Action

The management system takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Activities or methods such as risk based thinking, lessons learned from similar product or processes, fool-proofing, predictive maintenance are all utilized to identify opportunities for systematic improvements.

Reference Documents

235825	Incoming Quality Control Procedural Regulations
880032	Internal Corrective and Preventive Action Procedures
895729	Calibration Procedures
QAP0003	Calibration Control of Test and Measurement Equipment
WWD7630	Laboratory Standard ISO9001
QOP-DESIGN-017	Corrective and Preventive Action Procedure for Design Centers
WWD8520	Corrective Preventive Actions
SUB-CORRECTIVE-ACTION	Corrective Action System
999068-ERPF	Error Proofing Policy
999064-DFMEA	Design Failure Mode and Effects Analysis Policy
438001	Potential Failure Modes and Effects Analysis (PFMEA) and Control Plan
240113	Internal Quality Audit Procedure

QMS Process Interactions (Appendix A)



Appendix B
PROCESS INTERACTION FLOW FOR DESIGN ACTIVITIES

