SemiConductor Devices

SEMICONDUCTOR DEVICES

Quality

Manual

QPI0001

Rev. 16

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Revision History

Rev. #	ECR #	Description of change	Date	Originator
0	0001886	New Spec	10/2001	Alberto B.
1	0002484	Update according to Iso14000	07/2002	Alex I.
2	0002518	Minor changes according to the Standards institution's audit	08/2002	Alberto B.
3	0002714	Minor changes according to the Standards institution's audit	11/2002	Elena A.
4	0003109	Changes in the company's mission statement and the Quality policy	04/2003	Alberto B.
5	6379	Update according to OHSAS 18001	12/2003	Alex I.
6	11885	Update with Q.A. Organizational Structure change.	09/2005	Asaf Shavit
7	18092	Add a new version for ISO14001-	04/2006	Alex Itzkovitz.
8	22817	Update quality organization according to organizational changes.	07/2007	Maya F.
9	28417	Update quality organization according to organizational changes – Page 9	03/2008	Marina L.
10	31393	Major update: Adaptations to AS9100B	04/2009	Marina L.
11	42458	Minor adaptations to AS9100	05/2010	Marina L.
12	51865	1. Organization chart (quality manager became a member of the management), 2. Addition of reference document: "Quality system management" procedure QPI20.	10/2010	Marina L.
13	56340	Cross reference table: Addition of note regarding cross reference to SCD procedures. Sect. 1.4 Specify that clauses 7.5.1.4 in AS9100 is an "exclusion"	03/2011	Marina L.
14	69160	Updates according to AS9100 rev. C: Cross reference table and Chapters 1-5	01/2012	Marina L.
15	75702	Sect. 2.4.5 - Update of the organizational structure	07/2013	Marina L.
16	85181	Update of the organizational structure: Sect. 2.2, Sect. 2.4.2.2, Sect. 2.4.5.	11/2015	Tatyana S.

CONTENTS

CROSS REFERENCE TABLE

QUALITY MANUAL VS. AS 9100 / ISO 9001

AS9100 / ISO 9001	Quality Manual
3.1	5.01.1
3.2	5.01.2
3.3	5.01.3
3.4	5.01.4
4.1	3.1
4.2.1	3.2
4.2.2	1.4, 2.4.5
4.2.3	3.5
4.2.4	3.6
4.3	3.7
5.1	2.1
5.2	2.1
5.3	1
5.4.1	2.1
5.4.2	2.1
5.5.1	2.1, 2.4
5.5.2	2.2, 2.4
5.5.3	2.1, 2.4
5.6.1	2.3
5.6.2	2.3
5.6.3	2.3
6.1	2.1
6.2.1	4.1
6.2.2	4.1
6.3	2.1
6.4	4.2
7.1	5.02
7.1.1	5.03
7.1.2	5.04
7.1.3	5.05
7.1.4	Exclusion
7.2.1	5.1.1
7.2.2	5.1.1
7.2.3	5.1.1

AS9100 / ISO 9001	Quality Manual
7.3.1	5.2
7.3.2	5.2
7.3.3	5.2
7.3.4	5.2
7.3.5	5.2
7.3.6	5.2
7.3.6.1	5.2
7.3.6.2	5.2
7.3.7	5.2
7.4.1	5.3.1, 5.3.2
7.4.2	5.3.3
7.4.3	5.3.2.3
7.5.1	5.4, 5.4.1
7.5.1.1	5.4.2
7.5.1.2	5.4.7
7.5.1.3	5.4.5, 5.4.6
7.5.1.4	5.4.8
7.5.2	5.4.1
7.5.3	5.4.3, 5.4.4
7.5.4	5.4.9
7.5.5	5.5
7.6	5.4.6
8.1	6.1, 6.4
8.2.1	6.8
8.2.2	6.2
8.2.3	6.5
8.2.4.1	6.3
8.3	6
8.4	6.6
8.5.1	6.7
8.5.2	6.7
8.5.3	6.7

Detailed cross reference to SCD procedures, see procedure QPI20

0. Introduction

This quality manual's requirements implementation is aimed to improve quality, schedule and cost performance by reduction or elimination of organization-unique requirements and wide application of good practice.

Forward (AS9100):

To assure customer satisfaction, an organization must produce and continually improve safe, reliability products that meet or exceed customer and applicable statutory and regulatory requirements. The globalization of the industry and resulting diversity of regional and national requirements and expectations, have complicated this objective. Organizations have the challenge of purchasing products from suppliers throughout the world and at all levels of the supply chain. Suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

This quality manual promotes the adoption of a process approach when developing, implementing and improving the effectiveness of quality management system, to enhance customer satisfaction by meeting customer requirements. Such an approach emphasizes the importance of :

a) Understanding and meeting **customer requirements,**
b) The need to consider processes in terms of **added value**,
c) Obtaining **results** of process performance and effectiveness, and
d) **Continual improvement of processes** based on objective measurement.

The requirements specified in this manual are complementary (not alternative) to contractual and applicable statutory and regulatory requirements. Should there be any conflict between the requirements of this manual and applicable statutory or regulatory requirements, the latter shall take precedence.

0.1 Company Profile and Scope

Semiconductor Devices (SCD) was established in 1976 as the Israeli source for Infrared Detectors and Laser diodes.

The company is jointly owned by Elbit Systems Ltd. And Rafael (Armament Development Authority).

SCD's facility is located in the Galilee area, near the city of Karmiel. The 3100 sq. meter building includes Clean rooms, Crystal growth rooms, the VLSI design center, the Mask design and Radiometric centers, and Electrical and Environmental test labs.

Since 1976, thousands of SCD detectors have been used by clients in more than 25 countries worldwide.

0.1.1 Certifications

SCD's Quality Management System was awarded with ISO9001 certification in 1994 and with AS9100B in 2011 (Excluding clauses 7.5.1.4 in Rev. B or clauses 7.1.4 in Rev. C).

SCD's Environment, Health and Safety (EHS) Management System was awarded with ISO 14001 certification in 2002 and with OHSAS 18001 certification in 2004.

0.2 Custom Solutions

Semiconductor Devices (SCD) designs, develops and manufactures a full spectrum of infrared detectors and laser diodes. The company's advanced concepts and cutting-edge technologies have positioned it as one of the world's leading sources of these products.

SCD specializes in providing customized solutions that meet customer requirements. These include:

Mechanical and electrical adaptation of existing standard products.

New chip geometry designs.

Increased durability to comply with special environmental conditions.

Customized windows and filters.

SCD's detectors can be supplied at different degrees of integration, according to customer requirements and needs:

- Stand alone chips or FPAs
- Detector Dewar's
- Detector Dewar Coolers
- Detector Dewar Coolers and Electronics

0.3 Innovative Technologies and Products

SCD develops and manufactures a variety of cryogenically cooled IR detectors for the two main atmospheric window spectrum ranges:

- InSb (Indium Antimonide) detectors, for the MWIR (3-5 μm): Single Diodes, Linear arrays, Focal Plane 2D arrays.
- MCT (Mercury Cadmium Telluride) detectors, for the LWIR (8-12 μm): Linear arrays, TDI, and STDI.

SCD develops antimonide base compounds for the MWIR (3-5 μm) with high operating temperature.

SCD develops and manufactures a variety Uncooled IR detectors for LWIR applications

SCD develops and manufactures high power laser diodes for a variety of applications. SCD's laser diodes products include: QCW, CW

SCD devices can be used in harsh environments due to their unmatched robust design.

0.4 Quality First

All of SCD's products undergo a Total Quality Management program. This program includes managerial procedures, operating practices, testing, and monitoring of output. SCD's quality procedures, strong engineering abilities, speed, creativity and highly motivated work force have earned recognition from leading companies worldwide.

0.5 Customer Satisfaction

SCD provides the highest level of service to its customers. This includes process flexibility, customization, and high quality manufacturing. SCD's talented and motivated work force focuses on responding to customer needs and quickly expediting the customers' product into the market.

0.6 EHS Responsibility

SCD's management is committed to both the preservation of the environment and the well-being of its employees. SCD operates an EHS management system and invests the appropriate resources required for its successful implementation.

1. Quality Management System

1.1 Mission Statement (AS9100, sect. 5.3)

To be a leading "photo-detector house" for sensors working in the non-visible wavelength range.

To be a leading source for high power laser diodes

To develop our existing core capabilities into new business opportunities, in addition to our main business.

To contribute added value to the country, to the employees and to the stakeholders.

1.2 Quality Policy (AS9100, sect. 5.3)

SCD develops, manufactures and delivers products and services that provide a leading edge to its customers in their market-place.

The quality policy is based on the principles of Total Quality Management (TQM) and emphasizes the following:

- Customer satisfaction.
- Management leadership and commitment to quality.
- Involvement of all employees.
- Close relationships with vendors and sub-contractors.
- Process management and control by the use of advanced statistical techniques.
- Use of Concurrent Engineering during development.
- Continuous development and improvement.
- Controlled work plans based on quantitative goals and metrics.

1.3 EHS Policy ***(AS9100, sect. 5.3)***

SCD is committed to both the preservation of the environment and the well-being of its employees.
SCD's top management and employees are obligated to operate in accordance with all relevant external and internal legal requirements and procedures.
SCD's EHS policy complies with international standards for Environmental Management systems: ISO 14001, and for Occupational Health and Safety Management System: OHSAS 18001.

SCD's EHS policy is implemented by:
Promoting high level of awareness to EHS issues.
Preventing accidents, incidents and pollution.
Operating via strict EHS procedures.
Setting appropriate EHS objectives and targets for continuous improvement.
SCD's EHS policy is communicated to all persons working for or on behalf of the company, and is available to the public.

1.5 References

ISO 9001: 2008	Quality Management System
AS9100C: 2009	Quality Management System - Aerospace
ISO 14001: 2008	Environmental Management System
OHSAS 18001: 2008	Health and Safety Management Standard
QPI20	Quality Management System

2. Management responsibility

2.1 Management Commitment & Responsibility *(AS9100, sect. 5.1, 5.2, 5.4, 5.5.1, 5.5.3, 6.1, 6.3)*

It is top management responsibility to:

Ensure that **customer requirements and expectations** are understood and determined and are met with the aim of enhancing customer satisfaction and that appropriate action is taken if planned results are not, or will not be, achieved.

Ensure that product conformity and **on-time delivery** performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

Develop and implement the **quality management system** and continually improving its effectiveness by:

Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

Establishing the quality policy

Ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measured and consist with the quality policy.

Conducting management reviews (quality reviews), and

Ensuring the availability of resources.

Ensure that **Quality policy** is defined and communicated within the organization.

Ensure that the **responsibilities and authorities** are defined and communicated within the organization

Ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Ensure that the planning of the quality management system is carried out in order to meet the requirements for that system, as well as the quality objectives

Ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Determine, provide and maintain the **infrastructure** needed to achieve conformity to product requirements. Infrastructure includes:

Building, workspace and associated utilities

Process equipment (hardware and software) and

Supporting services (such as transport and communication)

2.2 Management Representative *(AS9100, sect. 5.5.2)*

V.P of IT & Logistics who is responsible for the Quality department is a member of the top management (see par. 2.4.5) and has responsibility and authority that includes:

Ensuring that processes needed for the quality management system are established implemented and maintained.

Ensuring the promotion of awareness of customer requirements through the organization

The organizational freedom to resolve matters pertaining to quality

The organizational freedom and unrestricted access to top management to resolve quality management issues.

2.3 Management Review *(AS9100, sect. 5.6)*

The Management Review of the Quality and EHS Systems is performed on a periodic basis and at least once a year to ensure that effective corrective and preventive action plans are implemented as needed.

The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

🗎 Records from management review are maintained by the quality manager.

The input to the management review includes information on:

Results of audits and status of preventive and corrective actions

Customer feedback

Process performance and product conformity

Follow up actions from previous management reviews

Changes that could affect the quality management system

Recommendations for improvement

Re-approve of quality policy

The output from management reviews include decisions and actions related to:

Improvement of the effectiveness of the quality management system and its processes

Improvement of product related to customer requirements

Resources needed

Continuing suitability and adequacy of the quality management system.

2.4 Organization ***(AS9100, sect. 5.5.1, 5.5.3, 4.2.2)***

a) The various responsibilities, and levels of authority of the personnel who manage, perform and verify the Quality and EHS Policy are defined by the following:

The organization charts

Specifications and operating procedures

SCD's objectives ,group goals and work objectives

b) The organizational structure can be modified in order to achieve the company's goals and objectives.

c) The description of the different processes of the Quality Management System and their interactions is described in QPI20.

d) The responsibilities of personnel for quality and EHS are as follows:

2.4.1 Chief Executive Officer

The CEO has the responsibility and authority to:

Lead SCD in performing its mission.

Ensure the existence of appropriate resources within the organization to meet the company's mission and goals.

Understand customer expectations and ensure that all SCD's employees understand and support SCD's customers.

Provide total customer support, both in technology and business issues.

To ensure that the company's quality and EHS goals and objectives are understood by everyone within the organization.

2.4.2 Quality manager

2.4.2.1 Quality Department

The mission of Quality department is to assure the compliance of SCD products to customer's needs and requirements.

The main responsibility of Quality department is to:

Ensuring reporting to top management on performance of the quality management system and any need for improvement

Ensure that personnel have access to quality management system documentation and are aware of relevant procedures.

Develop and implement quality assurance and quality control methodologies

Control critical stages in the process of development, production and supply of a product.

Quality department is independent in its decisions and has the authority to initiate and demand actions that will prevent deficiencies in products. Quality department has the authority to prevent supply of products that deviates from customer requirements.

2.4.2.2 Quality Manager

V.P of IT & Logistics who is responsible for Quality department reports directly to SCD's Chief Executive Officer. Quality department manager is responsible for:

Management quality reviews

Customer satisfaction reviews and corrective actions

Handling customer complaints and assuring implementation of appropriate corrective actions (including update of relevant quality procedures)

Writing and updating Quality manual and quality procedures

Ensuring that personnel have access to quality management system documentation (Quality Procedures) and are aware of relevant procedures.

Implementation of new quality standards / methodologies in order to improve product's quality

Managing quality department

2.4.2.3 Responsibility of project quality managers:

Projects quality managers have the authority to represent customer's needs and expectations in order to assure product compliance to customer requirements and expectations.

Projects quality managers have control on critical stages in product and project life cycle, as follows:

Project contract review

Product order review

Product design reviews: Critical Design Review (CDR) and Production Readiness Review (PRR)

Product qualification programs

Product qualification tests reports

First Article Inspection of new products

Product and process engineering changes

Product configuration (Product tree): Release for Development (DV), Design Freeze (DF) and Production (PR)

Supply of non standard products / products with deviations from quality requirements (MRB, NSPS)

In addition, project quality manager have responsibility to:

Guide the project manager and project team in quality requirements and quality procedures applicable for the project

Write quality program and update it according to progress in the project

Authorize new radiometric test equipment

Writ Acceptance Test Procedure check-list (ATP check-list)

Evaluate product reliability.

Be updated about quality problems in production line and products that were returned from the customer and assure implementation of preventive & corrective actions in new products/projects.

Support engineering in using quantitative methods for data analysis, gage reliability tests and statistical process control.

2.4.2.4 Responsibility of quality auditor

The responsibility of the Quality Auditor is to conduct Quality audits according to annual program and make follow up on corrective actions implementation.

2.4.3 EHS Manager

The EHS manager has the responsibility and authority to**:**

Manage the total operation of the EHS Policy.

Identify and assess all EHS aspects, impacts and risks.

Measure and monitor the significant EHS impacts and risks.

Propose the company's EHS objectives, targets and improvement programs.

Control all specifications and other documentation that may affect the EHS.

Provide EHS training to all employees and promote the implementation of the EHS Policy.

Provide EHS input in all operations including product and process development and purchasing.

Stop any activity in the plant that present a potential safety and or environment risk.

2.4.4 All Manager and Employees

a) It is the responsibility of each manager to ensure that each employee knows and understands SCD's Quality and EHS Policy; and to provide all the required means necessary to implement the Quality and EHS Policy.

b) It is the responsibility of each employee to know and understand the Quality and EHS Policy, and to perform his/her duties in a manner consistent with this policy.

c) All employees have the responsibility and authority to:

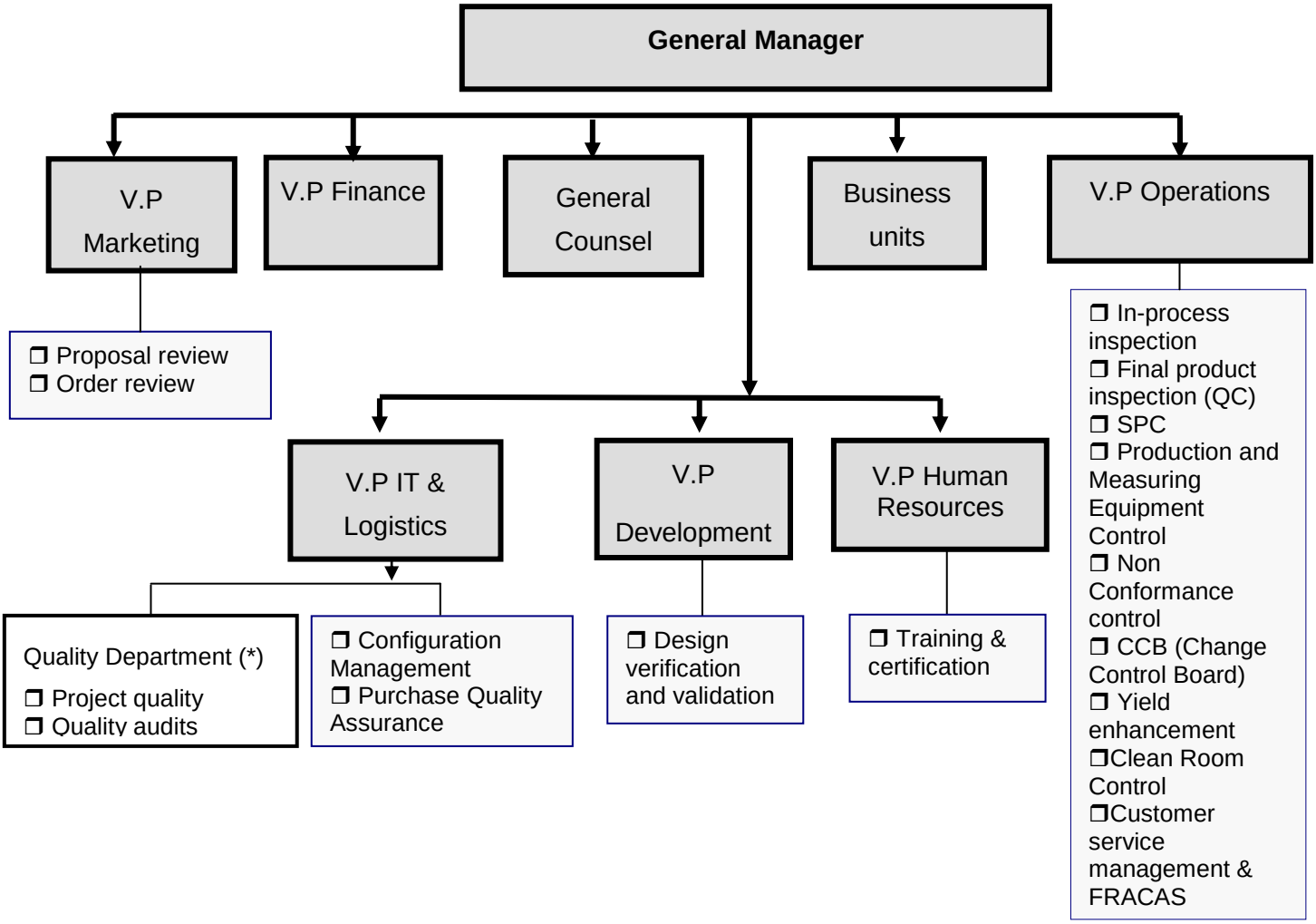
Take necessary action to prevent the production of non-conforming products, EHS accidents and incidents.

Report all product and process quality and EHS problems and initiate or recommend corrective actions.

Report all deviations from procedures and specifications to their immediate supervisor.

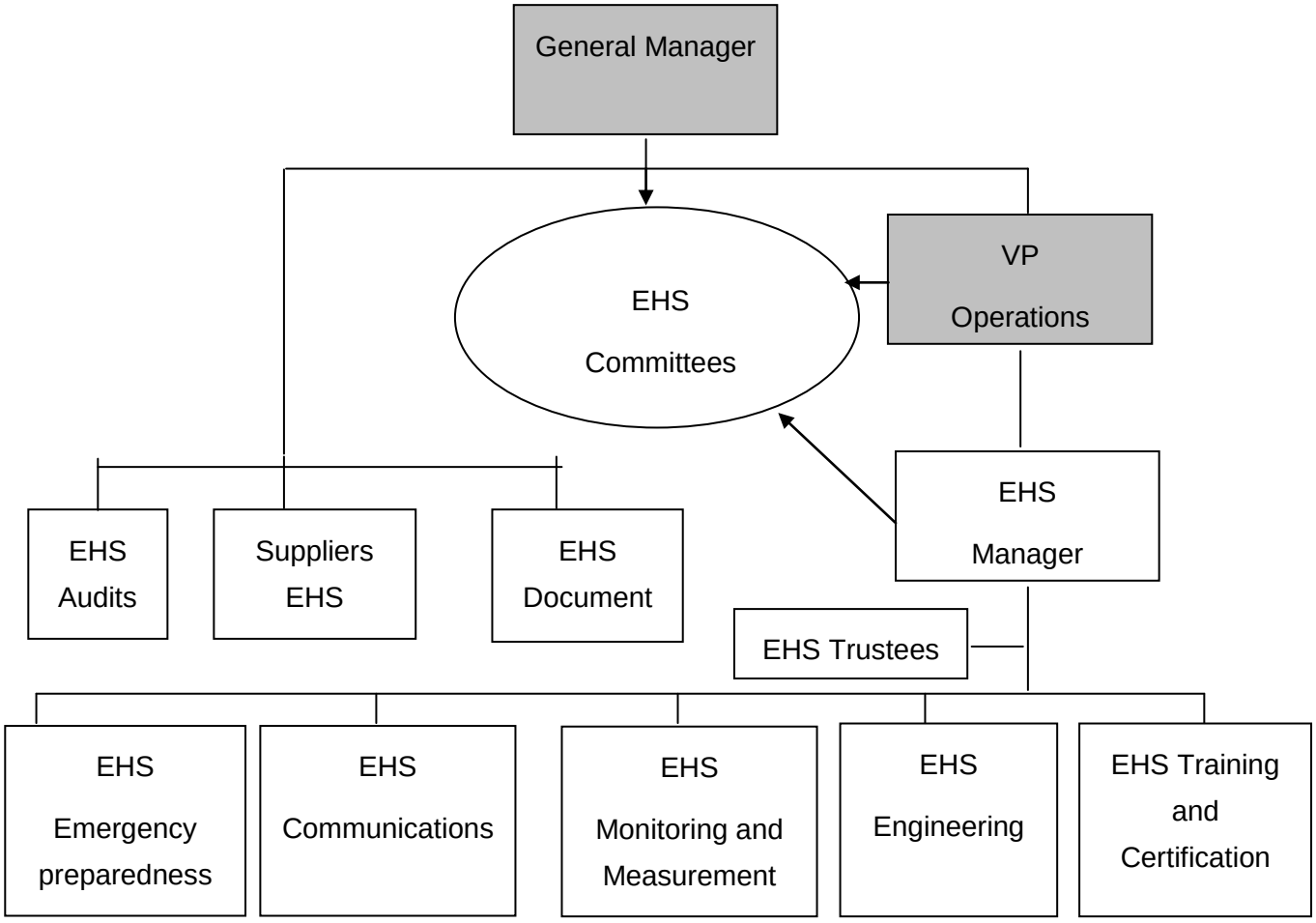
To be active in the process of continuous improvement.

2.4.5 SCD Organization Chart & Quality Functions



(*) Quality functions are deployed throughout the organization. Quality department has the professional responsibility for these functions.

2.4.6 EHS Organization



2.4.7 Quality and EHS Goals

Top Management is responsible for determining all quality and EHS goals, responsibilities and resources in order to realize all of the above-described objectives.

Goals are integrated into the quality and EHS system for every company function in order to achieve high quality manufacturing by reducing variation and preventing waste, and at the same time managing the environment and the employee's health and safety.

Teams and committees are created to:

- Continually check and verify success of achieved goals.
- Create and define projects that promote continuous improvement.
- Provide support and problem solving techniques for identifying and solving problems.
- Provide technical and logistical support to personnel responsible for projects.

2.4.8 Customer Satisfaction Measurement

SCD measures the level of customer satisfaction by the following methods:

- **The Quantitative Method:** Customer satisfaction surveys performed on a yearly basis
- **The Qualitative Method:** Performed through customer audits, performance reviews, and regular meetings with the customers.

Quality manager communicates the results of the surveys to top management through reports and management reviews. Project Managers communicate the results of technical meetings and reviews with the customers.

2.5 References

AS9100 / ISO9001	Section 5
Quality Management System	QPI20
Management responsibility	QPI10

3. Quality and EHS Management System

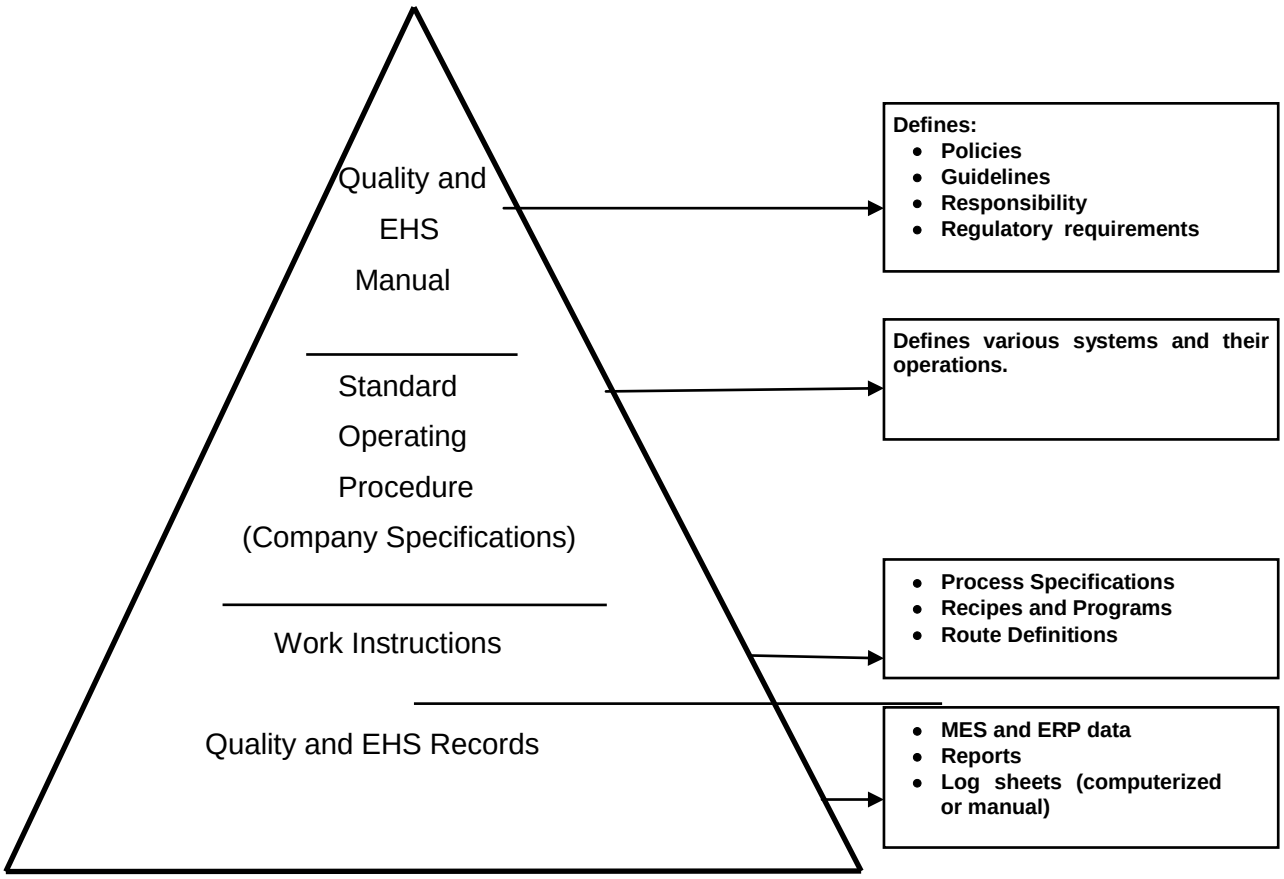
3.1 Policy ***(AS9100, Sect. 4.1)***

SCD's Quality and EHS Systems are aimed at meeting customer's requirements as stated in SCD's mission statement while protecting the environment and promoting safe work conditions and also aimed at meeting statutory and regulatory requirements related to quality system management. The Quality and EHS Systems as well as the Quality and EHS Manual are designed to conform to the standards defined in ISO 9001, ISO 14001, OHSAS 18001 and AS9100.

Quality management system is established, documented, maintained and its effectiveness is continually improved in accordance with the requirements of quality standards and customer needs.

Quality procedure QPI20 (Quality System) includes the identification of the processes needed for the quality management system, their application throughout the organization and the sequence and interaction of these processes.

3.2 Quality and EHS Systems Documentation Structure ***(AS9100, Sect. 4.1, 4.2.1)***



Quality systems documentation is maintained in PDM (Product Data Management) system. All personnel have access to that documentation and are aware of relevant procedures. Customer and/or regulatory authorities' representatives have access to quality management system documentation.

3.3 Quality Planning Documentation

Quality Planning Documentation is defined and documented in accordance with the checks and balances built into the Quality Policy. These include:

Contract reviews.

Design reviews.

Quality plans for new product.

Projected plant goals, updated and reviewed on a quarterly basis.

Employees' personal goals, reviewed quarterly.

The workflow process and work procedures, reviewed continuously.

3.4 Continuous Improvement

All employees are responsible for the continuous improvement of our products, services and plant EHS conditions. All organizational entities (Operations, Marketing, Development, etc.) are parts of the philosophy of continuous improvement. These entities all take part in establishing goals that improve quality, service, productivity, EHS, and reduce costs. Specific action plans for improvement regarding internal and external customers are created, including process, product, service and EHS quality.

3.5 Document and Data Control *(AS9100, Sect. 4.2.3)*

Documentation and data are controlled to ensure quality, reliability, and consistency. Documentation and Configuration Control department is responsible for:

- Developing and implementing a document control system for issuing, changing or deleting documents and test programs.
- Ensuring that all documents and test programs are approved by the appropriate authorized personnel prior to issuing, and at each change thereafter.
- Maintaining a list of all document user locations and ensuring that new documents, updates to existing documents, and document obsolescence notices are distributed to these locations.
- Maintaining a master list of all active documents denoting the document number, name and current revision.
- Notify those affected by a document change through e-mail or by sending a hard copy, whichever is needed for the document in question.

Document users are responsible for ensuring that only current revisions of documents are used. SCD coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements according to procedure QPI52.

3.6 Quality Records *(AS9100, Sect. 4.2.4)*

Quality and EHS Records are evidence of our Quality and EHS Policy's conformance to specified requirements. These records are clearly identified, stored and maintained to ensure reteriev ability.

🖹 All the Quality and EHS Policy records are maintained for a minimum period of time indicated in the reference procedures QPI160.

🖹 Procedure QPI67 define the method for controlling records that are created by and/or retained by suppliers.

Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

3.6.1 Responsibility and Methodology

a) Each department is responsible for establishing procedures to identify and collect applicable records and store them in their respective areas.

b) Each department is responsible for archiving records and ensuring that stored records are maintained to minimize deterioration and damage, prevent loss, and allow for quick retrieval.

c) Key records which are maintained include, but are not limited to, the following:

- Inspection and test results
- Material and product traceability
- Procedures and specification change orders
- Corrective action records
- Management reviews
- Calibration records
- Internal audit reports
- Customer complaints
- MES/ERP records
- Contract reviews
- Design reviews
- Qualification (Validation) results
- Environmental aspects and impacts, and health and safety risks.
- EHS objectives, targets and management programs.
- Legal and other EHS requirements.
- Records of EHS incidents.
- Protocols of EHS committee meetings.
- Records of communication with interested parties.
- EHS monitoring and measurement records.

3.7 Configuration Control ***(AS9100, Sect. 4.3)***

SCD established, document and maintain a configuration management process appropriate to its products. This process is documented in procedures no. QPI50 & QPI52

3.8 References:

AS9100 / ISO 9001	Section 4
Quality Management System	QPI20
Document control	QPI50
Configuration control	QPI52
First Article Inspection for purchased item	QPI67
Quality and EHS records control	QPI160

4. Resource Management

4.1 Human Resources ***(AS9100, Sect. 6.2)***

4.1.1 Policy

Personnel performing work affecting directly or indirectly (by performing any task within the quality management system) shall be competent on the basis of appropriate:

- Education
- Training
- Skills
- Experience

All manufacturing personnel are trained to perform their job functions and are certified only after passing successfully all required tests.

All manufacturing support personnel undergo a detailed training according to their job requirements.

Employee development programs are available for all SCD's personnel in order to maintain a high level of professionalism and ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

Training and/or employer development programs are defined based on job requirements.

4.1.2 Responsibility and Methodology

Human Resources are responsible for:

Determining the training needs for all personnel with their respective managers.

Developing and supplying tools and aids for training.

Establishing certification tests.

Providing orientation for all new employees and contracted personnel (including persons working on behalf of the company).

Providing documented guidelines for the implementation of non-certificate training programs for employees not involved in manufacturing.

Defining, publishing, and maintaining an annually training plan.

Maintain appropriate records of education, training, skills and experience.

4.1.2.1 Training Effectiveness

One or more of the following methods evaluates training quality:

Post-course testing

Internal audits

Job performance evaluation

Training evaluation questionnaire.

4.2 Work Environment ***(AS9100, Sect. 6.4)***

Due to the nature of the material being manufactured and technology being used, the control of the production areas environmental conditions are critical to the success of SCD's operations. Production areas environmental parameters are closely monitored for compliance to specified requirements

Some of the environmental controls are:

Airborne particle count.

Purity of de-ionized water.

ESD control.

Humidity and temperature.

In addition, SCD's operations on corporate strict EHS control mechanisms in order to protect its employees and the environment from excessive risks.

4.3 References

AS9100 / ISO 9001	Section 6
Quality Management System	QPI20
Education, Training and Certification	QPI180

5. Product Realization

5.0 Planning of product realization (AS9100, Sect. 7.1)

SCD's Quality Assurance department is responsible for writing a Product Quality Plan for every new product. These plans include requirements for risk analysis, design reviews, product qualification plans, purchase quality and EHS aspects.

The structure of Product quality plan and requirements for records needed to provide evidence that the realization processes and resulting product meet requirements, are defined in procedures QPI40 and MT0006.

5.01 Terms and Definitions: (AS9100, Sect. 3)

5.01.1 Risk:

An undesirable situation or circumstance that has both a likelihood of occulting and potentially negative consequence.

5.01.2 Special Requirements:

Those **requirements** identified by the customer, or determined by the organization, which have **high risks** to being achieved, thus requiring their inclusion in the risk management process.

Factors used in the determination of special requirements include: * Product or process complexity, * Past experience and * Product or process maturity.

Examples of special requirements include:

- Performance requirements imposed by the customer that are at the limit of the industry's capability or
- Requirements determined by the organization to be at the limit of its technical or process capabilities.

5.01.3 Critical Items:

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the production realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc. that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

5.01.4 Key Characteristic:

An attribute or feature whose variation **has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.**

NOTE: Special requirements, critical items and key characteristics are interrelated:

- Special requirements are identified when determining and reviewing requirements related to the product (see 7.2.1 and 7.2.2 in AS9100).
- Special requirements can require the identification of critical items.
- Design output (see 7.3.3 in AS9100) can include identification of critical items that require specific actions to ensure they are adequately managed.
- Some critical items will be further classified as key characteristics because their variation needs to be controlled.

5.01.5 Verification:

Process to ensure that the design and development outputs have met design and development input requirements,

5.01.6 Validation:

Process to ensure that the resulting product is acceptable of meeting the requirements for the specified application or intended use, where known

5.01.7 Traceability:

traceability requirements can include:

- Identification to be maintained throughout the product life,
- The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., scrap, delivery)
- For an assembly, the ability to trace its components to the assembly and then to the next higher assembly
- For a product, a sequential record of its production (manufacture, assembly, inspection /verification) to be retrievable

5.01.8 Special processes

Processes where the resulting output cannot be verified by subsequent monitoring or measurement and, as consequence, deficiencies become apparent only after the product has been delivered.

5.02 Planning of Product Realization

SCD plans and develops the processes needed for product realization. In order to do so, SCD determines the following, as appropriate for the product:

- Quality objectives and requirements for the product
- The need to establish processes and documents, and provide resources specific to the product
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and criteria for product acceptance
- Records needed to provide evidence that the realization processes and resulting product meet requirements
- Configuration management appropriate for the product
- Resources to support the use and maintenance of the product

5.03 Project Management:

Product realization shall be planed and managed in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints, according to procedure QPI40.

5.04 Risk Management:

Process for managing risk to the achievement of applicable requirements is established in procedure QPI46 and includes:

- Assignment of responsibilities for risk management,
- Identification of risks (e.g., likelihood, consequences, risk acceptance (See also definition of "special requirements" in sect. 5.01.02),
- Definition, assessment and communication of risks throughout product realization
- Identification, implementation and management of actions to mitigate risks that exceed the defined risks acceptance criteria,
- Acceptance of risks remaining after implementation of mitigating actions

5.05 Configuration Management:

Process for configuration management throughout product realization is established in procedures MT0005 and QPI52 and includes: configuration management planning, configuration identification, change control, configuration status.

Configuration audit is carried out as part of FAI process, according to procedure QPI42.

5.1 Contract review ***(AS9100, Sect. 7.2)***

5.1.1 Policy

SCD is dedicated to promoting long-term contractual relationships with its customers. All customer inquiries, invitations to tender, or order requests, are reviewed to ensure that SCD is fully capable of complying with all requirements as directly defined by customer or necessary for intended use and/or statutory and regulatory requirements related to the product.
Determination of requirements related to the product shall include:

- Requirements specified by the customer, including the requirements for delivery and post delivery activities, and special requirements
- Requirements not stated by the customer but necessary for specified or intended use, where known, including special requirements
- Statutory and regulatory requirements applicable to the products,
- Any additional requirements considered necessary.

5.1.2 Responsibility and Methodology

Requirements related to the product shall be reviewed. The review shall be conducted prior to SCD's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- SCD has the ability to meet the defined requirements
- Special requirements of the product are determined
- Risks (e.g., new technology, short delivery time frame) have been identified.

Contract review is generally a long and involved process of customer/supplier checks and balances, due to the complex nature of SCD’s products. A mutually satisfactory contractual relationship between SCD and its customers is built upon customer participation and interaction as described in the following:

The approval procedures for new or modified contracts including requirements for maintenance of records of the review and actions arising from the review, are described in procedures FN0220 & FN0219.

The initial pre-contractual stage involves an inter-disciplinary team with the participation of the Marketing, Development, Quality, EHS, and Process Engineering departments.
Routine customer/SCD conference calls, meetings and formal reviews, both at the pre-contractual and post-contractual stages, allow SCD and the customer to touch base on contractual issues, solve technical problems as they arise, and promote technical development.

5.1.3 Customer Communication

SCD determined and implemented effective arrangements for communicating with its customers in relation to:

- Product information – procedure QPI40
- Enquiries, contracts or order handling, including amendments – procedure FN0219, FN0220
- Customer feedback, including customer complaints – procedure QPI190

5.2 Design and Development ***(AS9100, Sect. 7.3)***

SCD has created a methodology for the design of new products to assure that their design meets customer requirements. Verification tests are performed in order to ensure that design outputs meet design inputs and customer expectations. Any change in the design initiated by the customer or by SCD must be validated before implemented. Design reviews are conducted at pre-defined stages of development in order to review the effectiveness of the design process.

The different design and development tasks to be carried out are based in the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements. Various EHS inputs are included in the design process. Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

The following table displays the various Design Reviews and the purpose of each:

Design Review	**Purpose**
PDR (Preliminary Design Review)	Review of the preliminary design and concepts, defines potential risks and contingency plans.
CDR (Critical Design Review)	Review and approve detailed final design of the items that will be used verification tests
FQR (Formal Qualification Review)	Review of design verification tests results, against product specification requirements.
PRR (Production Readiness Review)	Review full compliance of the product to specification requirements and readiness of the production line for serial production.

Procedure QPI40 and MT0007 includes the following:

a) Design and development planning (AS9100, Sect. 7.3.1):

b) Design and development inputs (AS9100, Sect. 7.3.2)

c) Design and development outputs (AS9100, Sect. 7.3.3)

- Meet the input requirements for design and development
- Provide appropriate information for purchasing, production and service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of product that are essential for its safe and proper use
- Specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items

d) Design and development review and authorization to the next stage (AS9100, Sect. 7.3.4)

e) Design and development verification (AS9100, Sect. 7.3.5)

f) Design and development review process & records

g) Control of design and development changes process & records

Procedure QPI45 and TXX6002 specifies:

- Design and development verification and validation documentation (AS9100, Sect. 7.3.6)
- Design and development verification planning, process & records
- Design and development validation planning, process & records (if relevant)

These tests are planned, controlled, reviewed and documented to ensure and provide the following:

- Test plans and specifications identify the product being tested and resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria
- Test procedures describe the method of operation, the performance of the test and recording of the results.
- The correct configuration of the product is submitted for the test
- The requirements of the test plan and the test procedures are observed
- The acceptance criteria are met.

The design and development documentation and records shall demonstrate that the product definition meets the specified requirements for all identified operational conditions.

Procedure QPI52 specifies:

- Control of design and development changes (AS9100, Sect. 7.3.7)

5.3 Purchasing (AS9100, Sect. 7.4)

5.3.1 Policy (AS9100, Sect. 7.4.1)

All materials which are incorporated into SCD products, selected materials which support the manufacturing process but do not directly affect the final product, and all sub-contracted services directly related to the end product, are purchased from approved suppliers.
SCD has responsibility for quality of all products purchased from suppliers, including customer-designed sources.
Where specified in the contract, the customer or the customer's representative are afforded the right to verify at the supplier's premises and SCD premises, that subcontracts conforms to specified requirements.

5.3.2 Responsibility and Methodology (AS9100, Sect. 7.4.1)

Purchasing Quality Assurance department has responsibility for approving supplier quality system. It has also the authority to disapprove the use of sources. It's responsibility also includes:
Initial certification of direct materials suppliers and sub-contractors, based on development recommendations according to QPI60 & 67.
Maintaining a register of approved suppliers that includes the scope of the approval
Insuring that only approved suppliers are used.
Define The necessary actions to take when dealing with suppliers that do not meet requirements
Determine and manage the risk when selecting and using suppliers
Define the process, responsibilities and authorities for the approval status decision, changes of the approval status and conditions for controlled use of suppliers depending on the supplier's approval status
Insuring that purchasing information includes all appropriate information (see sect. 5.3.3)
Assure implementation of General Quality Requirements for suppliers including notification of changes and obtain organizational approval where required (Document no. QPI160-GEN01)
Periodically review supplier performance. Records of these reviews are used as a basis for establishing the level of controls to be implemented.

Development department is responsible to define purchasing specification that describes the requirements for the product to be purchased including key characteristics and requirements for approval of product. It is required to ensure the adequacy of specified purchase requirements prior to their communication to the supplier

The EHS manager is responsible for outlining all EHS aspects and risks of the materials used in production processes, and sub-contractors performing activities within the plant boundaries.

The Purchasing department responsibility is to assure that purchase orders contain the essential data needed to define the requirements. When necessary, purchase orders contain a full specification of the materials being purchased. The purchase order also defines any special inspection or certification requirements (including EHS requirements).

5.3.2.1 Qualified Vendor List (QVL)

A qualified vendor list of raw material suppliers and subcontractors is maintained. Suppliers are only added to the list once they have been qualified and approved. Only materials purchased from suppliers in the list can be used for production.

5.3.2.2 Subcontractor Development and Evaluation

Suppliers are evaluated and selected based on their ability to meet quality, delivery, cost and EHS requirements. The supplier rating and ranking system is defined in QPI65.

5.3.2.3 Materials Specification and Verification *(AS9100, Sect. 7.4.3)*

Every purchase order defines the specification number for the applicable material. Incoming inspection of materials or source inspection is specified for each material type.

5.3.3 Purchasing Information *(AS9100, Sect. 7.4.2)*

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

Requirements for approval of product, procedures, process and equipment

Requirements for qualification of personnel

Quality management system requirements

Requirements regarding the need for the supplier to:

Notify SCD if nonconforming product

Obtain SCD approval for nonconforming product disposition

Notify SCD of any change that may affect Fit /Form/ Function /Logistics of the product (e.g., changes in product, process, suppliers, manufacturing facility location) and obtain SCD approval

Flow down to the supply chain the applicable requirements including customer requirements

record retention requirements

Right to access by SCD, its customer and regulatory authorities to the applicable areas of all facilities and any level of the supply chain involved in the order and/or to all applicable records.

5.4 Manufacturing and Services **(AS9100, Sect. 7.5.1-7.5.4)**

All manufacturing and manufacturing support operations are documented and monitored to ensure that they are carried out under controlled conditions.

5.4.1 Responsibility and Methodology

a) The Development and Process Engineering departments are responsible for developing, documenting, and implementing control procedures for the manufacturing process. Their responsibilities include:

Establishment of process controls and development of controls plans where key characteristics have been identified.
Identification of in-process verification points where adequate verification of conformance cannot be performed at late stage of realization
Design, manufacture and use of tooling so that variable measurements can be taken, particularly of key characteristics
Special processes
Provision for prevention, detection and removal of foreign objects.
Process and equipment operating procedures.
Process and product parametric limits.
Process and product parametric measurement methods.
Equipment maintenance procedures.
Inspection criteria and procedures.
Facility/environmental conditions.
EHS requirements.
Criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).

b) Each department is responsible for using ESD preventive measures and equipment as applicable.

c) Every employee or sub-contractor that enters the clean room must be certified for clean room procedures.

5.4.2 Productio Process Verification

A representative item from the first production run of a new assembly is used in order to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. These processes are repeated when changes occur that invalidate the original results (e.g. engineering changes).
The procedure is described in QPI42.

5.4.3 Product Identification and Traceability

Assigning serial numbers helps in identifying and tracing the progress of raw material inventory. Work in progress is fully traceable at all times, by means of a computerized floor shop tracking system (MES System).

Containers containing dangerous materials are labeled in accordance with the appropriate regulations in order to protect the employees and the environment.

5.4.4 Traceability

The Storage and Production departments are responsible for identifying all raw materials including their class, type, etc. Where appropriate, shelf life is clearly indicated to prevent the use of overdue materials.

All hazardous materials are stored in conditions that minimize risk to the employees and the environment.

The Production department is responsible for tracking all products in real time by updating the MES system when a product lot is transferred from one step to another in the manufacturing process.

5.4.5 Process Monitoring, Control, and Operator Instructions

The manufacturing activity conducted in SCD is based on a process flow showing the sequence of operations for each lot. Every operation is detailed in the controlled specification.

Production flow is controlled in real time by a computerized planning and monitoring software program.

Operators must be certified for each operation they perform. Criteria for workmanship are set where applicable such as certification to written standards, reference samples or illustrations showing the level of workmanship required.

Relevant tests are defined with specification limits and corrective actions to be followed if the tests are failed.

SPC is used to monitor key process parameters and product characteristics. Process capability goals are defined.

5.4.6 Inspection, Measuring, and Test Equipment

All instrumentation, tools, gages and other equipment used to control or monitor critical processes and all equipment used to measure or test products (as well as equipment used by sub-contractors monitoring and measuring EHS aspects and risks on site) are maintained in a calibration and maintenance system.

Procedure is detailed in QPI110

The Operations department maintains records of the calibration. This department is also responsible to define storage requirements, including periodic preservation/condition checks.

5.4.7 Process Changes

Changes to processes are documented in the Document Control system. The Engineering and Development departments define and perform qualification tests for process changes that may affect the quality of the product or EHS conditions before those changes are introduced. The Engineering and Development departments in cooperation with the EHS manager will incorporate DFE and risk assessment practices into process development and changes.

Change control procedure (QPI52) includes requirement to identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

5.4.8 Post Delivery Support

Post delivery support, including data collecting and analysis, in described in procedure QPI190 and RMA0001.

5.4.9 Customer Property

Care with customer property is described in procedure QPI70.

5.5 Handling, Storage, Packaging, Preservation and Delivery ***(AS9100, Sect. 7.5.5)***

All material and product inventories are handled, stored, packaged and shipped in a manner that prevents material or product damage and degradation, or adverse effects on the environment and employee safety.

5.5.1 Handling

The following wafer handling techniques are used during manufacturing and testing processes to protect products from damage or contamination:

Wafers are only handled with dedicated vacuum wands or tweezers.

Wafers are only transported in designated carriers and boxes.

Shipping and handling materials are ESD protected (static dissipative).

5.5.2 Storage

Suitable areas are provided for raw materials, parts, and finished products. Inventory control systems are in place for raw materials. (The first raw material stored is usually the first removed, unless otherwise specified.)

Finished products are stored in special protected areas before being delivered to customers.

All dangerous materials are stored in conditions that minimize risk to the employees and the environment.

5.5.3 Packaging

The Manufacturing and Engineering departments are responsible for ensuring that products are packaged in a manner suitable to protect the product during delivery. Control specifications are in place for packaging and labeling procedures.

5.5.4 Preservation

The preservation of products is maintained by using the handling, packing and storage procedures described above and in other documented procedures.

5.6 References

AS9100 / ISO 9001	Section 7
Quality Management System	QPI20
Design verification tests	QPI45
Design Control and transfer to Production	QPI40
Risk management	QPI46
Document control	QPI50
Configuration control	QPI52
Purchase quality management	QPI60
First Article Inspection for purchased item	QPI67
Firs Article Inspection for final product	QPI42
Care with customer property	QPI70
Customer service	QPI190

6. Measurement, Analysis & Improvement

(AS9100, Sect. 8.1, 8.2, 8.3, 8.4, 8.5)

6.1 Policy

SCD develops and maintains monitoring and test methods to verify the effectiveness of its processes, products and quality / EHS system. The test and monitoring methods are selected based on the ability to provide the required accurate information and drive a continuous improvement process.

6.2 Internal Quality Audits

Quality and EHS audits are conducted to determine:

The effectiveness of the quality and EHS systems of different activities in the organization.

The degree to which field work complies with this quality and EHS policy and manual, its documented procedures, groups objectives, success criteria, and standards requirements that SCD is certified for.

6.2.1 Responsibility and Methodology

The Quality Assurance department is responsible for:

Defining audit standards and procedures and submitting audit summaries to the management.

Assigning an independent certified auditor who coordinates and conducts audits.

Evaluating corrective action reports, making sure that root causes are identified and addressed.

Checking corrective actions for effectiveness.

6.3 Inspection and Testing

Inspection and test procedures are built into SCD manufacturing systems to monitor the effectiveness of various processes, compliance of the products to customer specifications and expectations and compliance to EHS legal and other requirements.

Process for the inspection, verification and documentation of a representative item from the first production run of a new part or following subsequent change that invalidates the previous first article inspection results is described in QPI42.

6.3.1 Responsibility and Methodology

The Purchase Quality Assurance department is responsible for defining inspection criteria and methods for inspecting incoming materials. This department also carries the incoming inspection.

Operations are responsible for the in-process inspection and final product inspection. The manager of final product inspection (QC) reports directly to the productions manager.

The Development and Process Engineering departments are responsible for establishing inspection criteria and control methods (including statistical controls as applicable) for process inspections (visual, electrical and radiometric).

The EHS manager is responsible for defining inspection criteria and methods for inspecting EHS aspects of materials and processes.

The EHS managers is responsible for evaluating compliance with applicable EHS legal and other requirements and report his findings and corrective actions to management.

6.4 Statistical Techniques

All critical processing steps are monitored and controlled utilizing statistical process control methods. Statistical techniques are also used to optimize process parameters, validate process changes, and to improve overall yield.

6.4.1 Responsibility and Methodology

Process Engineering department and Yield enhancement department are responsible for identifying the parameters that need to be monitored, and for establishing applicable statistical controls.

Development and Process Engineering are responsible for using statistical techniques (i.e., designs of experiments, analysis of variances, robust designs, etc.) when applicable in order to optimize process performance and robustness.

Quality Assurance department is responsible for providing guidelines for using statistical tools.

6.5 Control of Non-Conforming Products and Raw materials

All products and raw materials that do not conform to specified requirements or are suspected to be non-conforming, are identified, segregated from conforming products and materials, and handled according to specified procedure: QPI130 and QPI190.

6.5.1 Responsibility and Methodology

a) Production, Process Engineering, and Purchase Quality Assurance departments are responsible for controlling non-conforming products, including:

Identifying suspected non-conforming products and holding them for MRB decision.
Defining procedures to prevent the mixing of conforming and non-conforming products in their respective work areas.
Defining procedures for the quick disposal of non-conforming products including provisions for revising a product (including its re-inspection), sending a product on, or scrap of a product.

b) The Production, Incoming Storage, and Purchase Quality Assurance departments are responsible for controlling non-conforming raw materials, including:

Defining and documenting procedures to prevent the mixing of conforming and non-conforming raw materials in the stores.
Clearly identifying non-conforming raw material.

6.6 Data Analyses

Data collected from monitoring and measuring is investigated to prove the conformance and affectivity of quality and EHS management system.
As minimum, the data refers to customer satisfaction, product characteristics EHS performances and suppliers.

6.7 Corrective and Preventive Action

Corrective and preventive action is documented for all instances of actual and potential non-conformance affecting material or product quality and EHS performance.

Examples of preventive actions opportunities include:

- Risk management
- Error proofing
- Failure mode and effect analysis (FMEA)
- Information on product problems reported by external sources.

6.7.1 Responsibility and Methodology

a) Development and process Engineering departments are responsible for:

Reviewing process and product data to identify actual and potential non-conformance.

Documenting and implementing corrective actions and providing follow-up checks to ensure that the corrective actions are effective in preventing recurrence.

Analyzing raw material non-conformance and resolving with the supplier the required corrective action, including the follow-up.

b) Customer Service department is responsible for coordinating and monitoring customer returns and providing corrective action reports to affected customers.

c) Development department is responsible for:

Performing the necessary testing and experiments (DOE) to expose potential failure modes during process development.

Developing and implementing statistical process control techniques.

d) Yield Enhancement department is responsible for:

Ensuring root cause corrective actions for all major yield degradation, in order to prevent reoccurrence.

Initiating the necessary projects to achieve continuous improvement and reduce waste.

e) EHS manager is responsible for monitoring and coordinating corrective and preventative actions for all EHS incidents and non-conformances.

6.8 Customer Satisfaction

SCD monitors information relating to customer perception as whether the organization has met customer requirements and needs. This information includes:

- Product conformity
- On time delivery performance
- Customer complaints and corrective action requests

SCD develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

Customer complaints are monitored and handled by the Quality Assurance department. Corrective action plan is completed as soon as possible.
In the case of a product being returned, the Customer Service department performs a failure analysis. Final failure analysis reports are sent to the customers.
All communications with interested parties (including customers) regarding EHS issues are coordinated by the EHS manager.

6.9 References

AS9100 / ISO 9001	Section 8
Quality Management System	QPI20
First Article Inspection for final product	QPI42
Handling of nonconformance	QPI130
Customer service	QPI190