CUSTOMER SENSITIVE

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TITLE

QUALITY MANUAL

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Semiconductor Devices

QUALITY MANUAL

QPI0001 - QUALITY MANUAL / REV. 20

Revision History

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19	003396	Updates for QA department R&R and Management Representative Major updates of format across the document	11/2019	Ira M.
20	013522	Remove EHS indications, change company name from SCD to Semiconductor Devices Ltd, Major updates across the document	01/2024	Haim C.

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1. *Company Profile*

SEMICONDUCTOR DEVICES LTD (can be referred to as "SCD") company was established in 1976 as the Israel source for design, developing and manufacturing Infrared Detectors and Laser diodes. Our facility is located in the Galilee area, at the northern part of Israel. The 3000 sq. meter building is a solid base for all research and development activities as well as for unique high end FAB facility followed by mechanical, electrical and optical production technologies used for the assembly and testing of our world leading IR detectors.
SCD is a leading worldwide supplier of Infrared Detectors and Laser Diodes. Backed by more than 40 years of accumulated experience in development and manufacturing, SCD's products have been selected by leading companies all over the world, to become the core of their electro-optical systems, in the Defense, Home Land Security (HLS), and Commercial markets. SCD's unique capabilities and technologies are deployed in its extensive range of Cooled and Uncooled detectors based on a variety of sensing materials such as InSb, MCT, InGaAs, T2SL and VOx which are available in almost any video format: QVGA, VGA, XGA, HD.
SCD offers both off-the-shelf detectors and tailor-made solutions from all across the infrared spectrum: NIR, SWIR, MWIR, and LWIR.
We specializes in providing customized solutions that meet a customer requirements, which 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.

Mission Statement :

ALWAYS WHAT YOU NEED ***ALWAYS BY YOUR SIDE*** ***ALWAYS A STEP AHEAD***

Semiconductor Devices company aims to be a world leader in the development, production and sale of sensing detectors in the infrared field and powerful laser diodes. A global company that develops, manufactures, sells and supports systems at the forefront of technology, in order to create significant value for its customers, the company's employees, its owners and the security of the State of Israel.

2. *Quality System Purpose and Scope*

SCD has adopted and realizes the benefits of Quality Management Principles into our daily activities. The intent of the Quality Management Principles is to provide a foundation to continually improve upon the Company's performance. The organization management is committed to meet all applicable Statutory and Regulatory requirements. Statutory and regulatory requirements are integrated in the QMS and are identified during contract review activities and strategic planning.

3. *Applicability*

Based on an analysis of issues of concern, interests of stakeholders, and in consideration of its products and services, SCD has determined the scope of the management system as follows:

The design and manufacture of infra-red detectors and high power laser diodes

The Quality Management System, applies to all processes, activities and employees within the company, is certified to the International Quality Standards AS9100 revision D and ISO9001:2015, with no exclusions.

4. *Context Of The Organization*

4.1. The Organization and Its Context

SCD periodically review and analyze key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to SCD and its interested parties.

INTERNAL ISSUES	EXTERNAL ISSUES
Owners	Customers & Suppliers
Employees	Markets & Competition
Performance	Regulatory & Statutory
Capacity	Economic backdrop
Values & Culture	Cultural & Social
Innovation & Knowledge	Technological

Such issues are monitored and updated as appropriate and discussed as part of management reviews.

4.2. Needs and Expectations of Interested Parties

SCD periodically analyze the risks and opportunities recognized in the issues identified above (sec. 4.1) in terms of potential affect to its interested parties, their needs and expectations. "Interested parties" are those stakeholders who receive our products or services, or who may be impacted by them, or those parties who may otherwise be affected by company activities. These interested parties, their needs and expectations are identified and periodically reviewed per the document **Management Responsibilities QPI10**.
This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

INTERESTED PARTY	INT/EXT	Relations and Requirements
Customers	Ext	- Organizations which use the products and directly affect SCD's ability to satisfy their needs. - Understand the needs, expectations, and requirements.
Employee / Staff	Int	- Responsible for realization of SCD's products. - Expect work environment that will facilitate manufacturing of products which meet the needs of end customers.
Suppliers	Ext	- Provide components and materials for SCD's product. - Interested in long relationships based on mutual benefit.
Sub-contractors	Ext	- Provide sub-assemblies, manufacturing processes related to SCD's products - Interested in long relationships based on mutual benefit.
Parents Companies	Ext	Corporate agreements
Product End User	Ext	Users of SCD's customers products Want OTD and OQ
Certification Body	Ext	Assess conformity of SCD's QMS to AS9100D and is notified about changes to the QMS
IAQG	Ext	- Defines requirements for CB's, controls OASIS System - Requires membership
Regulatory Bodies	Ext	- Defines controlling regulations that impact on QMS and SCD's activity. - Demand compliance to regulations

4.3. Scope of the Quality Management System

SCD has determined the boundaries and applicability of the quality management system to establish our scope as follows:

The design and manufacture of infra-red detectors and high power laser diodes

This scope is based upon external and internal issues, requirements from relevant interested parties, and products and services we provide. All applicable requirements of AS9100 are applied in accordance with the scope of the quality management system. The scope is maintained and made available as documented information to interested parties. The scope identifies the types of products and services covered, and provides justification for any requirement determined as not applicable to our quality management system.

4.4. Quality Management System and its process

4.4.1. Organizational Core Processes (PEAR)

SCD has determined the core processes needed for the its management system and their application throughout the organization, as identified in **Annex 1**. Required process inputs, expected outputs, sequence and interaction have been determined. Process performance indicators are monitored to ensure effective operation, control and availability of resources. Assigned responsibilities, authorities and associated risks and opportunities have been determined for our core processes. Processes are periodically evaluated to ensure intended results are achieved with any needed changes implemented to improve the management system.

The following core processes and their KPI which have been identified for SCD:

Process Name	Process Owner	KPI
Development Process	VP R&D	Completion of mile stones
Purchasing	COO, Quality	Suppliers Quality Score
		Suppliers On-time Delivery Score
Manufacturing and assembly Process	COO	Customers On-time Delivery Score
		% of returned products
		Repair turn-around time (TAT)

4.5. Documented Information

SCD maintains the necessary documented information to support the operation of our processes. This retained information provides confidence that our processes are achieving planned results. Documented information includes: Description of processes and their application, process sequence and interaction, and assignment of responsibilities and authorities for these processes.

5. *Leadership*

5.1. Leadership & Commitment

5.1.1. General

Top Management continually demonstrates their leadership and commitment regarding our quality management system. Top Management is accountable for the effectiveness of the quality management system, and ensures that the established quality policy and objectives are appropriate for our company context and strategic direction. Our quality management system is integrated with our business processes through use of the process approach and risk-based thinking. Top Management demonstrates the importance of the quality system management by ensuring required resources are made available, and communicating that conformance to requirements is expected to achieve intended process results. All employees are supported and directed to contribute to the effectiveness of the quality management system thus promoting company-wide improvement. Top Management demonstrates support for all relevant management positions in accordance to their area of responsibility.

5.1.2. Customer Focus

Top Management demonstrates leadership and commitment regarding customer focus by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met. The risks and opportunities that can affect conformity of our products and services have been determined and action taken to enhance and maintain customer satisfaction. Product and service conformity and on-time delivery performance are monitored with appropriate action taken in the event planned results are not, or will not be, achieved.

5.2. Quality Policy and Objectives

5.2.1. Establishing the Quality Policy

Top Management has defined a Quality Policy that is appropriate to the purpose and context of our organization, and that also supports our strategic direction. The Quality Policy is the framework for creating our organizational Quality Objectives with each area satisfying goals relevant to the support of these objectives, including the commitment to continuous improvement.

The quality policy of SEMICONDUCTOR DEVICES LTD is as follow:

With our hearts and minds we

Encourage a culture of continuous improvement with involvement of all employees

Strive for excellence and quality in all facets of the company by management leadership

Maximize customer confidence by delivering on our promises

Design and deliver effective and reliable products and services

Comply with all applicable internal and external requirements

Maintain an effective and efficient quality management system

5.2.2. Communicating the Quality Policy

The Quality Policy is available and maintained as documented information within our quality management system. The Quality Policy is reviewed for continuing suitability during management review and all department managers are responsible for communicating how the Quality Policy applies to each employee's specific function. The Quality Policy is available to appropriate interested parties upon request or at our website: www.scd.co.il.

5.3. Organizational Roles, Responsibilities and Authorities

Top Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the ***Annex 3: Organizational Chart*** and Job Descriptions.
Top Management has assigned responsibility and authority for ensuring our quality management system conforms to the requirements of the AS9100 Standard (as well as other interested party required standards), ensuring that quality system processes deliver their intended outputs, reporting on process performance and identifying opportunities for improvement, promoting total customer satisfaction throughout our organization and ensuring the integrity of our quality management system is maintained when changes are planned and implemented.
Top Management has appointed a specific management employee of our organization as the management representative having the responsibility and authority for oversight of the quality management system. The management representative has the organizational freedom and unrestricted access to Top Management for resolving quality system issues.

6. Planning

6.1. *Actions to Address Risks and Opportunities*

6.1.1. Planning of our management system has considered issues regarding the context of our organization (section #4.1) and also the requirements of interested parties (section 4.2) to determine and address identified risks or opportunities. The planning of our management system provides assurance that our management system can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects and achieve improvement.

6.1.2. Top Management has planned the required actions to address the identified risks and opportunities of our quality management system. These actions have been integrated and implemented into our quality system processes, are proportionate to the potential impact on product conformity, and are evaluated for effectiveness.

6.2. *Quality Objectives and Planning to Achieve Them*

6.2.1. Top Management has established quality objectives at relevant functions, levels, and processes required by the quality management system. Our quality objectives are consistent with our quality policy, are measurable, account for applicable requirements, are relevant to the conformity of our products and services, enhance customer satisfaction, and are appropriately monitored, communicated and updated as required. Quality objectives and supporting information are documented and maintained.

6.2.2. When planning how to achieve our quality objectives, Top Management has determined what will be done, what resources will be required, has identified the responsible employees, and determined the expected completion time and how the results will be evaluated.

6.3. *Planning of Changes*

When changes to our quality management system are determined to be required, these changes are conducted in a planned manner. When planning such changes the Top Management considers the purpose and potential consequences of the change, the integrity of the quality management system, availability of resources, and the allocation or reallocation of associated responsibilities and authorities.

7. Support

7.1. Resources

7.1.1. Provisions of Resources

Top Management has determined and provided the necessary resources needed for establishing, implementing, maintaining and continually improving our quality management system. This planning has considered the capabilities of, and constraints on, existing internal resources and what may need to be obtained externally.

7.1.2. People

Top Management identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations and processes are qualified on the basis of appropriate education, experience or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

7.1.3. Infrastructure

Top Management has determined, provided, and maintains the infrastructure necessary for the operation of our processes and to achieve conformity of our products and services. This infrastructure includes buildings, utilities, equipment, hardware, software, transportation resources and information and communication technologies.

7.1.4. Environment for the Operation of Processes

Top Management has determined, provided, and maintains the environment necessary for the operation of our processes and conformity of our products and services. A suitable work environment for our product and service considers social, psychological and physical factors, such as non-discriminatory, calm, non-confrontational, ergonomics, workplace location, hygiene, cleanliness, temperature, humidity, lighting, protection from electrostatic discharge, stress-reducing, burnout prevention work methods and workplace safety.

7.1.5. Monitoring and Measuring Resources

7.1.5.1. Top Management has determined and provided the resources required to ensure that the monitoring or measuring of our products and services to requirements are reliably validated. These resources are suitable for the type of activity being undertaken, are maintained to ensure continuing fitness for use and have appropriate documented information retained as evidence.

7.1.5.2. **Measurement Traceability** is considered essential for providing confidence in measurement result validity. Measurement equipment is calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. In the event no such standards exist, the calibration method and subsequent verification documented information is retained. All measurement resources are identified providing status, safeguarded from adjustment, damage, or deterioration that may invalidate calibration status and associated measurement results.

SCD has established, implemented and maintains a recall process for monitoring and measuring equipment requiring calibration or verification. A register of monitoring and measuring equipment is maintained and includes equipment type, unique identification, location, calibration or verification method, frequency and acceptance criteria. This equipment may include test hardware, test software, automated test equipment, plotters used for verification data, and personally or customer supplied equipment used to provide evidence of product and service conformity. Suitable environmental conditions are defined for calibration or verification of our monitoring and measuring equipment. In the event equipment is found to be unfit for its intended purpose, previous measurement results are reviewed and appropriate actions taken as necessary.

7.1.6. Organizational Knowledge

SCD has determined the internal and external knowledge necessary for the operation of our processes and to achieve product and service conformity. This knowledge is maintained and available to the extent necessary to support our processes. When addressing the changing needs and trends of our industry, SCD considers current knowledge and determines how to acquire or

access any necessary additional knowledge or required updates in the effort to achieve our organizational goals.

7.2. Competence

Top Management (TM) has determined the necessary competence of person(s) doing work under our control that may affect performance and effectiveness of our quality management system. The TM ensures person(s) are competent on the basis of appropriate education, training or experience, and takes action, as applicable, to acquire the necessary competence and evaluate the effectiveness of the actions taken. Appropriate documented information is retained as evidence of periodic review of necessary competence.

7.3. Awareness

Top Management ensures that persons doing work under our control that may directly affect our products and services are aware of: the quality policy, relevant quality objectives, their contribution to the effectiveness and improved performance of our quality management system, the implications for not conforming to our quality system requirements, the current relevant quality system documented information and any proposed changes, their contribution to our product and service conformity, their contribution to product safety and the importance of ethical behavior.

7.4. Communication

Top Management has determined the internal and external communications and corresponding feedback relevant to our quality management system including what is communicated, when and with whom, how, and who is responsible for the communication.

7.5. Documented Information

SCD has determined the appropriate information required to be documented in accordance to the AS9100 standard and also as the information required for the effectiveness of our processes.

7.5.1. Creating and Updating

When creating and updating documented information, SCD has ensured appropriate identification, description, format and review and approval level required for suitability and adequacy, in accordance with procedure ***QPI51: Documented Information.*** The purpose of document control is to ensure that staff has access to the latest, approved information, and to restrict the use of obsolete information.
A documented procedure also define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling external origin information (customers and suppliers documents).
Configuration documents are subject to additional controls per section 8.1.2 below.
records control is applicable to those records which provide evidence of conformance to requirements; this may be evidence of product or service requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.
Access to this documentation is made available to all relevant employees, involved in operations essential to the effective functioning of the system, through the PLM and MES electronic documentation viewing system.

8. Operation

8.1. Operational Planning and Control

SCD plans, implements and controls the processes needed to meet the requirements for our products and services, and implements the actions determined during the planning of these processes (section #6) by: determining the requirements for the product, process, or service, establishing criteria for processes and product or service acceptance, providing resources to achieve product or service conformity and to meet on-time delivery, implementing process controls in accordance with the established criteria, determining, maintaining and retaining documented information to the extent necessary for ensuring processes have been carried out as planned and to demonstrate product or service conformity to requirements, determining the process controls needed to manage identified critical or key characteristics, engaging representatives of affected planning and control functions, providing the process and resources supporting use and maintenance of our product or service, determining products and services to be obtained from external providers, and establish controls required to prevent the delivery of a nonconforming product or service to our customer.
SCD has planned and manages product or service provision (project management) in a structured and controlled manner appropriate to our organizational, product, service and the customer's requirements. This includes scheduled events conducted in a planned sequence to meet requirements at acceptable risk and within resource and schedule constraints. The output of this planning process is suitable for our operation with the control of planned changes, and the review of consequences of unintended changes, allow mitigating actions to be taken as deemed necessary. SCD ensures that outsourced processes are controlled.
SCD has established, implemented and maintains processes to plan and control the temporary or permanent transfer of work and to ensure the continuing conformity of the work to requirements. These processes ensure that work transfer impacts and risks are managed.

8.1.1. Operational Risk Management

SCD has planned, implemented, and controls processes for managing operational risks to the achievement of applicable requirements including those appropriate to our organization, products and services. Operational risk management identifies the assignment of responsibility, risk assessment criteria, identification, assessment, and communication of risks throughout operations, identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and the acceptance of risks remaining after implementation of mitigating actions.

8.1.2. Configuration Management

SCD has planned, implemented, and controls a process for ***configuration management QPI50*** appropriate to our organization, products and services ensuring identification and control of physical and functional attributes throughout the product lifecycle. This process controls product identity and traceability to requirements including implementation of identified changes, and ensures that the documented information is consistent with the actual attributes of the product or service.

8.1.3. Product Safety

SCD has planned, implemented, and controls an appropriate process required to ensure product safety during the entire product life cycle. Product safety information such as installation instructions enhance this process.

8.1.4. Prevention of Counterfeit Parts

SCD has planned, implemented, and controls processes appropriate for our organization and product; for the prevention of counterfeit or suspect counterfeit part use or inclusion into products delivered to our customers. Our process considers GIDEP notifications and verification or testing of supplied electronic component items relevant to our products and services.

8.2. *Requirements for Product and Services*

8.2.1. Customer Communication

SCD ensures effective communication with our customers by providing information related to our products and services, handling enquiries, contracts or orders, including changes, obtaining customer feedback and complaints relating to product or service, handling and controlling customer property, and when relevant the establishing of specific requirements for contingency actions.

8.2.2. Determining the Requirements for Products and Services

When determining the requirements for our products and services offered to our customers, SCD ensures that; the requirements for the product or service is defined including any applicable statutory and regulatory requirements and/or those considered necessary by our organization, claims offered for the product or service are met, special requirements for the product or service are determined and operational risks have been identified.

8.2.3. Review of the Requirements for Products and Services

8.2.3.1 SCD ensures that proper planning has provided the ability to meet the requirements for products and services to be offered to customers. Before committing to supply products and services to the customer, SCD conducts review including: requirements specified by the customer including delivery and post-delivery activities, requirements not stated by the customer but necessary for the proper use of specified or intended product when known, organizational requirements, statutory and regulatory requirements applicable to our products and services, and contract or order requirements differing from those previously expressed. Contract or order requirement review is coordinated with applicable functions of our organization, if review determines that some customer requirements cannot be met or only partially addressed, SCD will negotiate a mutually acceptable resolution with the customer. For contract or order requirements differing from those previously defined, as well as when the customer does not provide documented order requirements, product or service requirements are resolved and confirmed before order acceptance.

8.2.3.2 Required documented information is retained for the results of order or contract review, and on any new requirements for the product or service.

8.2.4. Changes to Requirements for Products and Services

SCD ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements when the requirements for products and services are changed.

8.3. Design and Development of Products and Services

8.3.1. General

SCD has established, implemented and controls a process for design and development suitable for ensuring the provision of our products and services.

8.3.2. Design and Development Planning

The design and development process defines stages and controls that consider the nature, duration, and complexity of our design and development activities, the required process stages including applicable design and development reviews, verification and validation activities, developmental responsibilities and authorities, internal and external resource needs, the control of interfaces between persons involved in the design and development process, involvement of the customer or end user, requirements for provision of the product or service, required controls expected for the design and development process by customers and other interested parties and the documented information needed for demonstrating that design and development requirements have been met. Dependent upon complexity, the design plan may be structured into distinct activities whereby each activity defines the required tasks, resources, responsibilities, design content, inputs and outputs, and the ability to provide, verify, test and maintain our products and services.

8.3.3. Design and Development Input

Requirements essential for our types of products and services to be designed and developed considers functional and performance requirements, lessons learned from previous similar design and development activities, statutory and regulatory requirements, standards and practices that our organization has committed to implement, the potential consequences of failure due to the nature of the product or service and the applicable potential consequences of obsolescence. Design and development inputs are adequate, complete and unambiguous. Conflicting design and development inputs are resolved as well as corresponding documented information retained.

8.3.4. Design and Development Controls

Controls applied to our design and development process ensure that the results to be achieved are defined, periodic reviews are conducted to evaluate our ability to meet design and development requirements, verification activities are conducted to ensure design and development outputs meet the input requirements, validation activities are conducted to ensure our resulting product or service meets the requirements for the specified application or intended use, necessary actions are taken on problems detected during review, verification, or validation, retaining documented information of these activities, authorization for progression to the next design plan stage and include representatives of functions concerned with the design and development stage being reviewed.

8.3.4.1 Tests necessary for verification and validation activities are planned, controlled, reviewed, and documented to ensure and provide evidence that test plans or specifications identify the test item and the required resources, test objectives and conditions are defined, parameters to be recorded and the relevant acceptance criteria, test procedures identify test method to be used and how to perform and record test results, confirming that correct configuration of the test item is used for testing, the test plan and test procedure requirements are observed and acceptance criteria are met. Monitoring and measuring devices used for testing are controlled per requirements of the AS9100 and ISO9001 standards. At completion of our design and development process, test reports, calculations and test results are retained as documented information demonstrating that the design for the product or service meets the specification requirements for all operational conditions.

8.3.5. Design and Development Output

Our design and development process ensures that design outputs meet input requirements, are adequate for the provision of our products and services, include appropriate monitoring, measuring and acceptance criteria, specify product or service characteristics that are essential for their intended purpose and their safe and proper provision, indicate any applicable critical item, including key characteristic, and specific actions required for these items and are approved by authorized personnel prior to release. Data required to allow the product to be identified, manufactured, verified, used and maintained is defined as well as supporting documented information retained.

8.3.6. Design and Development Changes

Design changes to our products or services are identified, reviewed and controlled either during or subsequent to the design and development process ensuring there is no adverse impact on conformity to requirements. Our design and development process defines criteria for customer notification, prior to implementation, of changes that may affect their requirements. Documented information is retained for design and development changes, results of design reviews, authorization of design changes and the actions taken to prevent adverse impacts. Design and development changes are controlled in accordance with the configuration management requirements defined in the AS9100 standard.

8.4. Control of Externally Provided Processes, Products and Services

8.4.1. General

SCD maintains documented procedures to ensure that externally provided processes, products, and services conform to specified requirements. SCD maintains responsibility for the conformity of all externally provided processes, products, and services including those sources defined by our customers. When designated by our customers, approved external providers and sources, including special processes, are used. Risks associated with the use of such external processes, products, or services, as well as the selection and use of these external providers, are identified and managed. Appropriate controls are applied to external providers and require that these providers flow-down appropriate controls to their direct and sub-tier external providers to ensure that requirements are met. Controls to be applied to externally provided processes, products, and services are determined when the externally provided product or service is intended for incorporation into our own products and services, are provided directly to the customer by the external provider on behalf of our organization, or when a process, or part of a process, is provided by an external provider as a business decision of our organization. Criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers has been determined and applied based upon their ability to provide processes or products and services to requirements. Documented information of these activities is retained including any necessary actions arising from these evaluations.

8.4.1.1 SEMICONDUCTOR DEVICES LTD has defined our process, responsibilities and authorities for the approval status decision, changes of this approval status, and the conditions for controlled use of external providers in accordance with their approval status. A register is maintained of these external providers that includes approval status and the scope of the approval. External provider performance is periodically reviewed including process, product and service conformity, as well as on-time delivery, with necessary actions taken when external providers do not meet requirements. Requirements are provided for controlling documented information created and/or retained by external providers.

8.4.2. Type and Extent of Control

Documented quality system processes ensure that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. Externally provided processes are subject to the controls required by our quality management system that define both the controls applicable to the external provider and their resulting output. Consideration is given to the potential impact of the externally provided process, product, or service upon our ability to consistently meet customer and applicable statutory and regulatory requirements. Effectiveness of controls applied to the external provider and the results of periodic external provider performance review, as well as necessary verification activities, ensure that the externally provided process, product or service meets requirements.

Verification activities for externally provided processes, products, and services are performed in accordance to the risks identified by our organization. These activities include applicable inspection or periodic testing when there is high risk of nonconformities including counterfeit parts. Our organization is responsible for provisioning acceptable processes, products, and services that comply with requirements regardless of any other interested party verification activities. Verification activities for our external providers include, but are not limited to, review of requested certifications for material, process, product, or service, test reports, manufacturing records, on-site quality system assessment, inspection of products or verification of service upon receipt and review of any delegations to the external provider. When externally provided product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

In the event our organization delegates verification activities to an external provider, the scope and delegation requirements are defined and a register of delegations maintained. Delegated verification activities are periodically monitored to ensure continued effectiveness. When external provider test

reports are utilized to verify externally provided products, a system is in place to select and validate the accuracy of raw material test reports through a third party. This process ensures that effective process and controls are in place for the validation and qualification of externally provided documented information.

8.4.3. Information for External Providers

Purchase order requirements are reviewed for adequacy prior to communication to the external provider. This communication ensures that our external providers possess the requirements for the process, product, or service being provided including identification of relevant technical data. SEMICONDUCTOR DEVICES LTD also communicates to external parties our requirements for the approval of products, services, methods, processes, equipment and the release of products and services. Requirements are also communicated for competence and qualification of relevant persons, interaction between our organization and the external provider, control and monitoring of the external providers' performance as applied by our organization, verification or validation activities to be conducted at the external providers premises by our organization or our customer, design and development control, special items, critical items, key characteristics, tests, inspections, process verifications, use of statistical techniques for product or service acceptance and related instructions for acceptance as defined by our organization.

Communication to external providers also defines their need to implement a quality management system, use customer-designated or approved external providers including those performing special processes, notifying our organization of any nonconforming process, product, or service and obtaining an authorized approval for disposition, preventing the use of counterfeit parts, notifying our organization and obtaining prior approval for any changes to processes, product, or service, external provider or location of manufacture, flow-down of requirements including customer requirements, provide test specimens for design approval, inspection, investigations or audits and ensure retention time and disposition requirements for documented information is defined. SEMICONDUCTOR DEVICES LTD, our customers, and regulatory authorities require right of access to all applicable areas of facilities and documented information, at any level of the supply chain. This activity ensures that affected persons are aware of their contribution to the conformity of products and services, product safety and the importance of ethical behavior.

8.5. Production and Services Provision

8.5.1. Control of Production and Service Provision

SCD has implemented production and service provision under controlled conditions that include, as applicable, the availability of documented information defining the characteristics of the products being produced, services to be provided, activities to be performed, the results to be achieved, availability and use of suitable monitoring and measuring resources, implementation of monitoring and measuring activities at appropriate stages to verify criteria for control of processes or outputs, and acceptance criteria for products and services have been met. Monitoring and measuring activities for product acceptance provides documented information that includes the criteria for product acceptance and rejection, where in the manufacturing sequence verification operations are performed, measurement results retained as evidence of acceptance or rejection, and required monitoring and measuring equipment with associated instructions for use. When sampling is used as a means of product acceptance, the sampling plans are based upon recognized statistical principles, standards, or based upon criticality of the product and/or the process capability. Documented information also defines the use of suitable infrastructure and environment for operating our processes and the appointment of qualified or competent persons. For special processes whereby the resulting output cannot be verified by subsequent monitoring and measurement, validation and periodic revalidation is conducted to confirm

planned results are achieved. Additional controlled conditions include the implementation of actions to prevent human error, implementing release, delivery, and post-delivery activities, established workmanship criteria, accountability of all products during production, identified critical item and key characteristic control and monitoring in accordance with documented processes, methods for measuring variable data are defined, the identification of in-process inspection points when adequate verification of conformity cannot be performed at later manufacturing stages, documented evidence demonstrating that all manufacturing, inspection and verification operations have been completed as planned, provisions for the prevention, detection, and removal of foreign objects and the control and monitoring of utilities and supplies that may affect conformity to product requirements. Products for use in production are not released until after completion of all required measuring and monitoring activities.

8.5.1.1. Control of Equipment, Tools and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to their final release and are maintained. Requirements are defined for the storage of production equipment and tooling including periodic preservation checks.

8.5.1.2. validation and Control of Special Process

For our processes where the resulting output cannot be verified by subsequent monitoring or measurement, SEMICONDUCTOR DEVICES LTD has established relevant validation arrangements such as defining criteria for the review and approval of the process, maintaining conditions for the process approval, approval of facilities and equipment, qualification of persons, use of specific methods and procedures for implementation and monitoring the process and retaining appropriate required documented information.

8.5.1.3. Production Process Verification

SCD has implemented production process verification activities to ensure our production processes are able to produce products that meet requirements. A representative item from the first production run of a new part or assembly is used to verify that the production processes, production documentation, and tooling are able to provide parts and assemblies that meet requirements. If a change occurs that invalidates the original results this process is repeated. First Article Inspection (FAI) standard AS9102 is recommended template for use to document and retain the results of production process verification.

8.5.2. Identification and Traceability

SCD uses suitable means for identifying outputs when it is necessary to ensure conformity of our products and services. Identification of the configuration of the product or service is maintained to identify any differences between the actual configuration and the required configuration. Status of outputs are identified regarding monitoring and measurement requirements throughout production and service provision. Acceptance authority media are used and controls established. Outputs are controlled with unique identification and traceability is enabled by corresponding retained documented information.

8.5.3. Property Belonging to Customer or External Provider

SCD exercises care when handling or using customer or external provider property while under our control. The property provided for use or incorporation into our products and services is identified, verified, protected, and safeguarded. In the event such property is lost, damaged, or otherwise found to be unsuitable for use, documented information on what has occurred is retained and reported to the customer or external provider.

8.5.4. Preservation

During product or service provision, outputs are preserved to the extent necessary ensuring continued conformity to requirements. Preservation includes identification, handling, contamination control, packaging, storage, transportation and protection. When required by specification or in accordance with statutory or regulatory requirements, preservation of outputs include provisions for cleaning, prevention, detection, and removal of foreign objects, special handling and storage for sensitive products, marking and labeling including safety warnings and cautions, shelf life control and stock rotation, and special handling and storage for hazardous materials.

8.5.5. Post Delivery Activities

SCD ensures post-delivery activities associated with our products and services meet their requirements. The extent of post-delivery activities required considers statutory and regulatory requirements, potential undesired consequences associated with the product or service, the nature, use, and intended lifetime of the product or service, customer requirements and feedback, collection and analysis of in-service data, the control, updating, and provision of technical documentation related to product use, maintenance, repair, and overhaul, controls for any work undertaken outside our facility, and customer support. In the event problems are detected after delivery, appropriate investigative and reporting action is taken. Post-delivery activities can also include warranty provision, recycling, and final disposal instructions.

8.5.6. Control of Changes

SCD reviews and controls changes for production and service provision to the extent necessary for ensuring conformity with requirements. Persons authorized to approve production or service provision changes are identified. These changes can include those affecting processes, production equipment, tools or software programs. Documented information describing the results of the review of changes, persons authorizing the change, and any necessary actions arising from the review are retained.

8.6. Release of Products and Services

SCD has implemented planned arrangements at appropriate stages to verify our product or service meets requirements. Products and services are not released to the customer until the planned arrangements have been completed or unless authorized by a relevant authority and, as applicable, by the customer. ***Documented information is retained on the release of products and services including evidence of conformity with the acceptance criteria, and traceability to the person(s) authorizing the release. To demonstrate product qualification, documented information is retained providing evidence that the product or service meets requirements. Documented information required to accompany the product or service is provided at delivery.***

8.7. Control of Non-Conforming Outputs

8.7.1. Outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery. Nonconforming outputs include nonconforming product or service generated internally, received from an external provider, or identified by a customer. Appropriate action is taken based upon the nature of the nonconformity and its effect on conformity of our products and services. This activity also applies to nonconforming products and services detected after the delivery of products or during or after the provision of services. Our nonconformity control process is maintained as documented information including provisions for defining responsibility and authority for review and disposition of nonconforming outputs and the process for approving persons making these decisions, taking necessary action to contain the effect of the nonconformity on other processes, products, or services, reporting in a timely manner nonconformities affecting delivered products and services to our customers and relevant interested parties (e.g., external providers, customers), and defining corrective actions for nonconforming products and services detected after delivery as appropriate to their impact. Nonconforming outputs are addressed by correction activities, segregation, containment, return or suspension of the product or service, customer notification, and obtaining authorization for acceptance

under concession by a relevant authority and when required by the customer. Nonconforming product dispositions of use-as-is, or repair, are only implemented after obtaining approval from an authorized representative responsible for the design, or after documented authorization is provided by our customer; in the event the nonconformity results in a departure from the contract agreement. Product dispositioned for scrap is conspicuously and permanently marked and/or positively controlled until physically rendered unusable. Counterfeit, or suspect counterfeit parts are controlled to prevent reentry into the supply chain. When nonconforming outputs are corrected, verification to requirements is conducted demonstrating conformity.

8.7.2. Nonconforming output documented information is retained that describes the nonconformity, actions taken, any concessions obtained, and the identification of relevant authorities making the decisions.

9. Performance Evaluation

9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

SCD evaluates the performance and effectiveness of our quality management system and has determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results, when monitoring and measuring shall be performed, and when the results from monitoring and measurement shall be analyzed and evaluated. Appropriate documented information is retained as evidence of the results.

9.1.2. Customer Satisfaction

SCD has implemented a process for obtaining, monitoring, and reviewing customer perception information (e.g., customer complaints, product rejections and returns, trends in on-time delivery, customer surveys, customer scorecard) to an extent ensuring their needs and expectations have been fulfilled. Information monitored and used for evaluating customer satisfaction include, but are not limited to, product and service conformity, on-time delivery performance, customer complaints and corrective action requests. Customer satisfaction improvement plans have been implemented that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3. Analyses and Evaluation

Appropriate data and information arising from monitoring and measurement, or from relevant external sources, are analyzed and evaluated including use of statistical techniques. The results of this analysis are used to evaluate conformity of products and services, the degree of customer satisfaction, quality management system performance and effectiveness, planning and implementation effectivity, effectiveness of actions taken to address risks and opportunities, external provider performance, and the need for improvement of our quality management system.

9.2. Internal Quality Audits

9.2.1. Internal audits are conducted at planned intervals providing information on whether our quality management system conforms to our own quality management system requirements, the requirements of the AS9100 and other relevant standards, and is effectively implemented and maintained. Internal audit results provide performance indicators, when applicable, to verify the quality management system is effectively conducted and maintained.

9.2.2. An audit program has been planned, established, implemented and is maintained that includes the frequency, methods, responsibilities, planning arrangements, reporting required, and that considers the importance of the process concerned, changes effecting our organization, and the results of previous audits. Our audit program defines the criteria and scope for each audit, the selection of auditors and their conduct during audits ensuring objectivity and impartiality of the audit process, ensure that audit results are reported to relevant management, taking appropriate correction and corrective actions without undue delay, and the retention of documented information as evidence of the audit program and subsequent audit results.

9.3. Management Review

9.3.1. Top Management reviews the quality management system at planned intervals ensuring its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of our organization.

9.3.2. Management Review Inputs

Management review is planned and carried out taking into consideration the status of actions from previous management reviews and changes to external and internal issues that are relevant to our quality management system. Information on the performance and effectiveness of our quality management system includes trends for customer satisfaction, relevant interested party feedback, the extent to which our quality objectives have been met, process performance and the conformity of products and services, nonconformities and corrective actions, monitoring and measuring results, audit results, external provider and on-time delivery performance. Management review also considers adequacy of resources, the effectiveness of actions taken to address risks and opportunities, and opportunities for improvement.

9.3.3. Management Review Outputs

Outputs of our management review process include decisions and actions related to opportunities for improvement, the need for any changes to our quality management system, resource needs, and identifying risks. Documented information is retained as evidence of the results of management reviews.

10. *Improvement*

10.1 General

SCD has determined and selected opportunities for improvement and has implemented any necessary actions to meet our customer's requirements and enhance customer satisfaction. These improvement opportunities include improving products and services to meet requirements as well as to address future needs and expectations, correcting, preventing, or reducing undesired effects, and improving the performance and effectiveness of our quality management system.

10.2 Nonconformity and Corrective Action

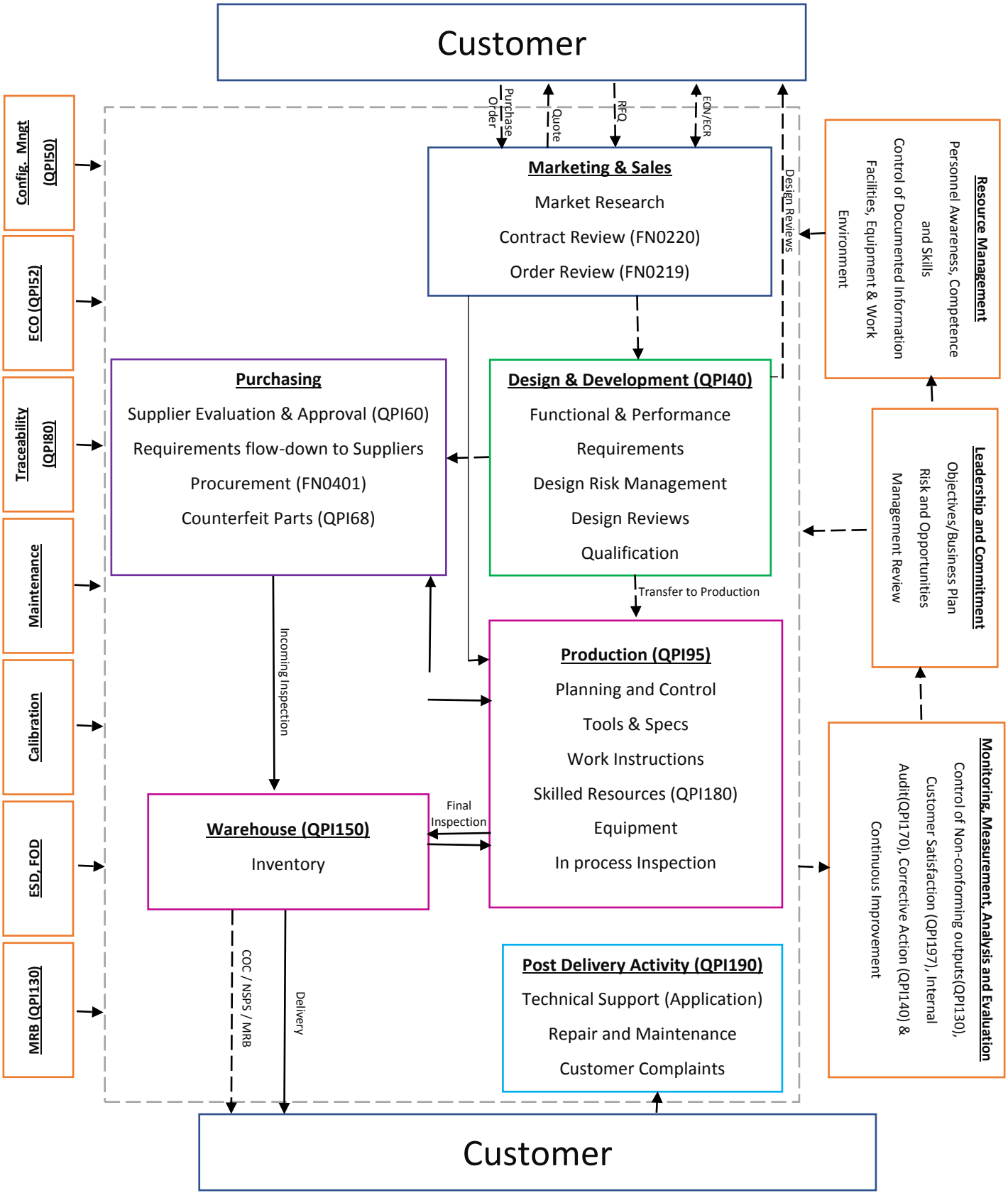
10.2.1 When a nonconformity occurs, including any arising from complaints, our organization reacts to the nonconformity and takes applicable action to control and correct the problem and deal with the consequences. SEMICONDUCTOR DEVICES LTD evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere; by reviewing and analyzing the nonconformity, determining the causes of the nonconformity including applicable related human factors, and determining if similar nonconformities exist or could potentially occur. Other corrective action activities include implementing action needed, reviewing effectiveness of any corrective action taken, updating risks and opportunities determined during planning as necessary, making changes to the quality management system as necessary, flowing-down corrective action to an external provider when it is determined that the external provider is responsible for the nonconformity, and taking specific actions when timely and effective corrective actions are not achieved. Corrective actions taken shall be appropriate to the effects of the nonconformities encountered. Documented information is maintained that defines our nonconformity and corrective action management processes.

10.2.2 SCD retains documented information as evidence of the nature of the nonconformity and any subsequent actions taken, and the results of any corrective action.

10.3 Continual Improvement

SCD continually improves the suitability, adequacy, and effectiveness of our quality management system. This process considers the results of analysis and evaluation, and the outputs from management review to determine if there are needs or opportunities for continual improvement that shall be addressed. Implementation of improvement activities are monitored to evaluate the effectiveness of the results.

Annex 1: Overall Process Sequence and Interaction



Annex 2: Correlation matrix to AS9100D Paragraphs

Subject	Procedure No.
4 Context of the organization	Title
4.1 Understanding the organization and its context	QPI0001
4.2 Understanding the needs and expectations of interested parties	QPI0001
4.3 Determining the scope of the quality management system	QPI0001
4.4 Quality management system and its processes	QPI10
5 Leadership	Title
5.1 Leadership and commitment	QPI0001
5.2 Policy	QPI0001,QPI20
5.3 Organizational roles, responsibilities and authorities	QPI0001
6 Planning	Title
6.1 Actions to address risks and opportunities	QPI10
6.2 Quality objectives and planning to achieve them	QPI20
6.3 Planning of changes	QPI0001
7 Support	Title
7.1 Resources	QPI0001
7.1.1 General	QPI0001
7.1.2 People	QPI0001
7.1.3 Infrastructure	QPI0001
7.1.4 Environment for the operation of processes	QPI0001
7.1.5 Monitoring and measuring resources	QPI0001
7.1.6 Organizational knowledge	QPI0001
7.2 Competence	QPI77
7.3 Awareness	QPI0001
7.4 Communication	QPI10
7.5 Documented information	QPI50
8 Operation	Title
8.1 Operational planning and control	QPI95
8.1.1 Operation risk management	QPI46
8.1.2 Configuration management	QPI50
8.1.3 Product safety	QPI40
8.1.4 Prevention of counterfeit products	QPI68
8.2 Requirements for products and services	QPI43
8.3 Design and development of products and services	QPI40
8.4 Control of externally provided processes, products and services	QPI60
8.5 Production and service provision	QPI90
8.5.1 Control of production and service provision	QPI90
8.5.1.1 Control of equipment, tools and software programs	QPI90
8.5.1.2 Validation and control of special processes	QPI220
8.5.1.3 Production process verification	QPI42
8.5.2 Identification and traceability	QPI80
8.5.3 Property belonging to customers or external providers	QPI70
8.5.4 Preservation	QPI150
8.5.5 Post-delivery activities	QPI190
8.5.6 Control of changes	QPI52
8.6 Release of products and services	TQC6703 QPI100
8.7 Control of nonconforming outputs	QPI130

9 Performance evaluation	QPI20
9.1 Monitoring, measurement, analysis and evaluation	QPI200
9.1.1 General	QPI200
9.1.2 Customer satisfaction	QPI197
9.1.3 Analysis and evaluation	QPI200
9.2 Internal audit	QPI170
9.3 Management review	QPI10
10 Improvement	Title
10.1 General	QPI20
10.2 Nonconformity and corrective action	QPI140
10.3 Continual Improvement	QPI20

Annex 3: Organization Chart