Quality Systems Manual

ISO 9001:2015
ISO 13485:2016

Power Designers Sibex (PDS)

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1.0 General: Power Designers Sibex (PDS)

Formed in 1983, Power Designers PDS (PDS) was incorporated as a multifunctional electronic manufacturing business in Clearwater, Florida. Since that time, this Veteran-Owned Small Business (VOSB) moved its corporate and sales headquarters to Crystal River with production in Crystal River and Homosassa Florida locations.

PDS has over 85,000 square feet of combined manufacturing area but our employees are the essential elements of our success. The core management team averages over 20 years of training & experience and every employee adheres to our high professional standards.

PDS has enjoyed the privilege of partnering with a diverse collection of customers from the military, medical, industrial and commercial markets. We offer experience, excellent quality, competitive pricing, advanced capabilities, production capacity and financial stability.

PDS business strategy is to continue to supply our customers with complex electronics, electromechanical products and sub-assemblies with best in class quality and service that exceeds our customers' expectations. PDS accomplishes this through the continual commitment of our top management and employees to comply with the requirements of, to review suitability, maintain and continually improve our quality management system.

"PDS's vision is to be a recognized leading United States Veteran Owned EMS (Electronic Manufacturer Service) provider of Quality Products and Services by means of Integrity and Honesty, building a corporation that will stand for Generations as a responsible employer of our communities.

2.0 Quality management principles

This quality manual describes the quality system principles applicable to the requirements of the ISO 9001:2015 and ISO 13485:2016 standards (See Correspondence Table 1). Each element reflects our commitment to quality as seen through the requirements of these standards, the needs of our customers, and PDS defined quality goals and objectives.

These principles include:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidenced based decision making
- Relationship management

It is a PDS quality goal to maintain and continually improve its ISO 9001:2015 and ISO 13485:2016 Quality management system.

3.0 Process approach / risk based thinking / (Plan do check Act) PDCA

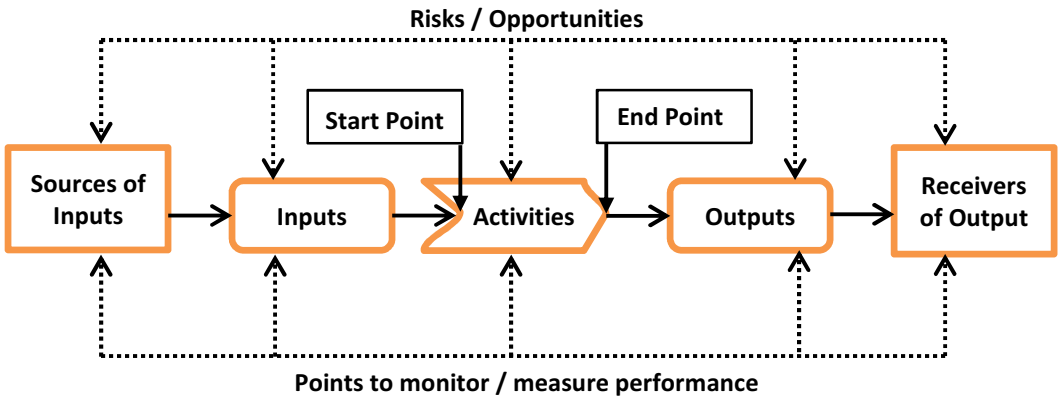
This quality manual promotes the adoption of a risk based thinking and process approach when developing, implementing, maintaining, and improving the effectiveness of a quality management system to enhance customer satisfaction by meeting customer requirements. See **Figure 1** below.

When used within a quality management system (QMS), such an approach emphasizes the importance of:

- Understanding and consistency in meeting customer and regulatory requirements
- The need to consider processes, in terms of added value
- The achievement of effective process performance
- Obtaining results of process performance and effectiveness, and continual improvement of processes based on objective measurements

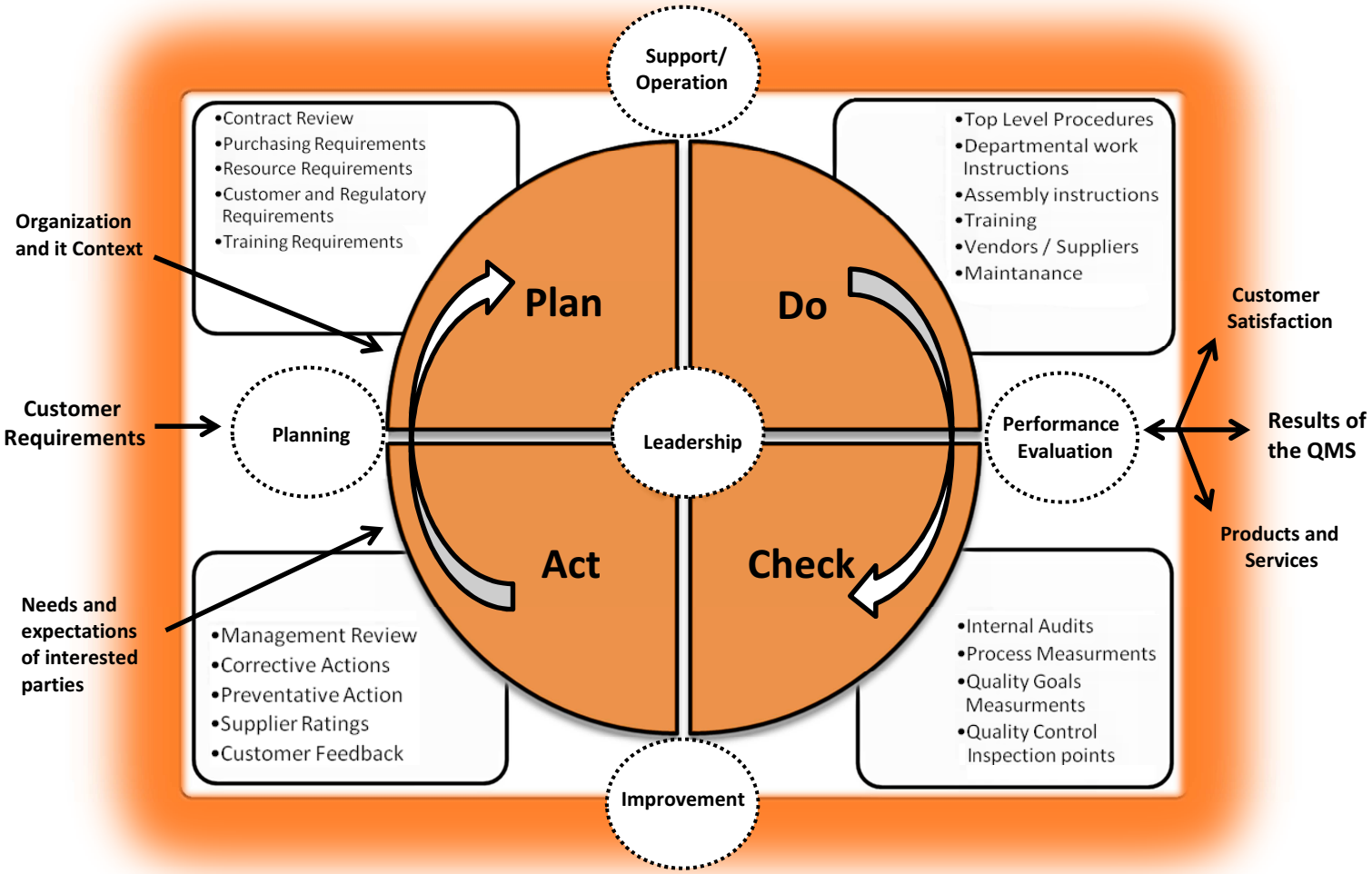
Addressing these in the QMS increases the effectiveness of the system, achieves improved results and prevents negative effects.

Figure 1: Schematic diagram of the elements in a single process



The **Plan Do Check Act** (PDCA) process cycle is not only applied to manufacturing processes, but also to the quality management system as well. **Figure 2** shows the PDCA cycle as it applies to the ISO9001:2015 and ISO13485:2016 standards.

Figure 2: PDCA cycle representation



4.0 Organization and context

4.1 PDS organization and its context

PDS has determined the internal and external issues relevant to our purpose, our strategic direction, and those that may affect our ability to achieve the QMS intended results. Internal and external issues within the scope of PDS QMS are monitored and reviewed. (See Appendix A)

4.2 PDS interested parties and their requirements.

PDS understands and has identified the interested parties and their expected requirements. This is to ensure PDS can consistently provide products and services to meet these expectations and also meet applicable statutory and regulatory requirements. Interested parties information within the scope of PDS QMS is monitored and reviewed.
(See Appendix B)

4.3 Scope of the PDS quality management system (QMS)

The scope of this PDS quality management system (QMS) in reference to ISO9001:2015 includes the design and development, assembly, and testing of electrical and electromechanical products. This may include cable assemblies, box builds, surface mount or through-hole printed circuit board assemblies and the conformal coating of them. PDS designs and produces these assemblies for military, aerospace, and commercial applications.

The role of PDS is that of a manufacturer and the scope of this PDS Quality management system (QMS) in reference to ISO13485:2016 includes assembly and testing of electrical and electromechanical medical assemblies. This may include cable assemblies, surface mount or through-hole printed circuit board assemblies and the conformal coating of them. PDS does not produce any finished medical devices at this time, only the sub components to them. Regulatory reporting requirements, for finished medical devices, are the customer's responsibility.

This manual defines the requirements for PDS to manufacture, assemble and test these assemblies as described in Standard Industrial Classification (SIC) 3672 and per ISO9001:2015 and ISO13485:2016 standards.

All sections of the ISO 9001:2015 standard are applicable to the PDS QMS. The following sections of the ISO13485:2016 standard are not applicable to the PDS QMS:

- 7.3 Design and Development
  PDS does not design or develop medical devices.
- 7.5.3 Installation
  Installation of products produced by PDS is completed by the customer, end user, or service provider
- 7.5.4 Servicing
  Servicing of products produced by PDS is completed by the customer, end user, or service provider
- 7.5.5 Particular requirements for sterile medical devices
  PDS does not produce sterile medical devices
- 7.5.7 Particular requirements for validation of processes for sterilization
  PDS does not produce sterile medical devices
- 7.5.9.2 Particular requirements for implantable medical devices
  PDS does not produce implantable devices.
- 8.2.3 Regulatory reporting
  PDS does not have regulatory reporting requirements for medical devices. This is the customer's responsibility

4.4 PDS Quality Management Systems and it processes

PDS has an established QMS; it is documented, implemented, maintained and continually improved. It defines how PDS meets regulatory requirements and how it ensures compliance through internal audits. PDS also has a system in place to review, evaluate, and address customer satisfaction through a process of continuous improvement. This quality manual and the PDS QMS ensure:

- The processes needed are identified (See Appendix C)
- The sequence and interaction of these processes is documented (See Appendix C)
- Inputs required and the outputs expected from these processes are determined
- Responsibilities and authorities are determined for these processes (See Appendix D)
- Criteria and methods needed to ensure that both the operation and the control of these processes are effective and have been documented
- Resources and systems necessary to support, monitor, measure, evaluate and continually improve the processes are provided
- Risks and opportunities are continually monitored

5.0 Leadership

5.1 Leadership and commitment

Top management plays a key role in the QMS by demonstrating leadership and commitment of the QMS to all interested parties. Taking accountability for the effectiveness of the QMS, ensuring the quality policy (SX-000-01-003) and objectives are established, documented, communicated, and compatible with the context and strategic direction of the organization. Ensuring the QMS is integrated into the business processes as a whole, providing the required resources, and promoting the process approach and risk based thinking.

Top management ensures the QMS achieves its intended results and promotes improvement upon those results. They communicate the importance of an effective quality management system and the importance of conforming to its requirements. They direct and support persons, including other relevant management personnel, to engage in and contribute to the QMS, thereby demonstrating their leadership in their area of responsibility.

They communicate the importance of customer, regulatory and statutory requirements to all PDS employees ensuring these are determined, understood and met. This is achieved, among other means, through:

- An established Quality Policy (SX-000-01-003)
- Management reviews
- Employee training
- Communicating quality objectives and measurements
- New Product Readiness meetings and reviews

Top management ensures risks and opportunities for improvement of the products is determined and acted upon keeping the focus on customer and other interested parties satisfaction.

5.2 Policy

Top management has established, implemented, and maintained a quality policy which is appropriate to the context of the business and its purpose. It is strategic and provides a framework for the quality objectives of the organization. It includes a commitment to improvement the QMS and to satisfy applicable regulatory requirements.

The policy is documented, maintained and available to relevant parties. It is communicated and understood within the organization.

Responsibilities and authorities are assigned, communicated and understood to ensure:

- The QMS conforms to requirements of the ISO Standards
- The processes are delivering intended outputs
- The performance of the QMS is reported including opportunities for improvement
- Continued promotion of customer satisfaction
- Changes to the QMS are reviewed and the integrity is maintained

Top management ensures that all personnel performing or verifying work have sufficient independence and authority to perform the required tasks. The interrelation of personnel managing, performing or verifying work is documented in the organizational chart and in work instructions. (See Appendix D)

6.0 Planning

6.1 Risk and opportunity

Quality management system planning is carried out as to meet the requirements as determined in the context of the organization. These include risk and opportunities to continually improve and enhance the QMS, prevent and reduce negative results, and give assurance the QMS can achieve it intended results.

These risks and opportunities are evaluated based on the potential impact on product conformity. The actions are integrated, implemented and evaluated for effectiveness.

6.2 Quality objectives and planning

PDS quality objectives have been established at relevant functions and processes. They are relevant to and consistent with the quality policy and are documented within the QMS.

When planning the quality objectives PDS determines what is to be done; what resources are required; who is responsible; when it will be completed and how to evaluate the results.

These objectives are communicated, measurable, monitored and results are reviewed and updated to ensure the objectives are being met and remain consistent with the quality policy.

6.3 Planning of changes

Changes to the QMS are carried out in a determined manner. Considerations include resource availability and allocation of them, responsibilities and authority changes, the general purpose of the change, the possible results and the effect on the integrity of the QMS.

7.0 Support

7.1 Resources

Resources are provided by PDS to ensure implementation, maintenance and continual improvement of the QMS. Resources required for addressing regulatory requirements, customer requirements, external providers, personnel, infrastructure, working environment, process equipment, materials, and information is provided.

The determination of these resource needs is completed during management review meetings, contract reviews, new product readiness reviews and training evaluations. It is based on current equipment constraints, organization knowledge and what may need to be obtained from external providers. Determination of these requirements is also made through customer feedback, internal audits and monitoring / measuring activities.

7.1.1 Monitoring and measuring resources

Monitoring and measuring activities used to demonstrate product conformity of predetermined requirements. The equipment required for completing this, shall be documented in build work instructions and is available at points of use. These activities are reviewed and approved prior to use.

All measuring test equipment which could affect the quality of the finished parts will be calibrated by an external sub-contractor or in-house, in accordance with PDS procedures. See (SX -000-02-001) Records of these calibrations will be maintained.

PDS will also ensure that:

- Calibration of equipment is performed prior to use and at regular intervals. The basis for the calibration is traceable to a national standard. The basis for calibration where no such standard exists will be recorded.
- Adjustments to equipment will be made as required, and records of these adjustments maintained
- Equipment requiring calibration is adequately identified as to the calibration status
- PDS equipment will be handled, cleaned, maintained and stored properly
- The equipment will be safeguarded from adjustments invalidating the calibration or measurement results
- Equipment is traceable through the asset management database to the area or department it resides in.

If equipment is found out of calibration, the previous calibration records will be assessed and any possible required actions regarding the equipment and effects on product requirements will be determined, acted upon and recorded.

Monitoring and measuring software used for final product verification will be confirmed prior to use and re-confirmed at specific intervals as required by customer. New or significantly revised computer software used in the QMS will also be validated prior to use. See (SX-000-02-019)

7.1.2 Organizational knowledge as a resource

Knowledge acquired through internal and external sources is maintained and available to the extent necessary. This knowledge may be captured in the product master document file and fed back into the design function to ensure this knowledge is incorporated into current and future designs. Organizational knowledge may be kept in the form of addition of information to documented work instructions, statistical data, quality records, corrective actions, complaints, repair data, etc.

When addressing changing needs or trends PDS considers the current knowledge it has and determines how to acquire or access additional knowledge when necessary.

7.1.3 Infrastructure

PDS has determined and documented the criteria for and provides the infrastructure to achieve conformity to product requirements and to ensure facilities are clean, maintained, and environmentally controlled. This also includes providing the infrastructure to prevent product mix up and to promote orderly handling of product. Adequate workspace, software, hardware, equipment, information systems, and transportation are available and maintained to perform all processes within the QMS.

Where process equipment maintenance could affect product quality, the required maintenance activities have been documented including the frequency.

7.1.4 Work Environment

The work environment is air-conditioned and each person is provided with a workspace and associated equipment/furniture to be able to perform their tasks. Employees are kept from completing repetitive tasks through cross training, and large amounts of overtime to promote good psychological health, and provided an environment supporting of good social behavior such as a non-confrontational and non-discriminatory atmosphere. The physical work environment is controlled for temperature, lighting, cleanliness, and noise conditions.

Where work environment is required to be monitored and controlled, as to avoid having an adverse effect on product quality, the requirement(s) will be included in the procedure for product development.

PDS has documented procedures for health, cleanliness and clothing of personnel, to prevent adverse effect to the quality of the product. See (SX-000-02-013). Additional requirements are specified in product work instructions and assembly procedures.

PDS has planned and documented arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of additional product, personnel or work environment.

Invasive and sterile medical devices are not supplied by PDS; therefore work environment and contamination controls required in terms of sterilization do not apply. This includes the training of and monitoring of these requirements. (See section 4.3)

7.2 Competence

PDS has documented the processes for establishing competence, providing needed training and ensuring awareness of personnel performing work effecting quality of product. See (SX-000-02-007).

Personnel at PDS are aware of the relevance and importance of their activities in regards to the QMS and how they contribute to the quality objectives. PDS ensures they have adequate experience, skills, training and education to fulfill their responsibilities as it affects product quality. The necessary competence is determined and available. This competence may come from training, skills, education or previous experience.

PDS evaluates the effectiveness of training, and the effectiveness of actions taken, to ensure personnel performing work effecting quality of product continually meet the required competence. This evaluation is based on the level of risk associated with the work the training is being provided for.

Any tasks, customer or regulatory requirement, that are identified as requiring specific skills, training, education or qualifications will be addressed, the resources will be provided for, and records of training will be kept. Proper training will be provided, or proper supervision will be available for personnel having been identified as working under special environmental conditions.

Appropriate records of specialized certifications, education, training, skills and previous experience are maintained. See (SX-000-02-007)

7.3 Awareness

The quality manager has the responsibility of promoting awareness of regulatory requirements and QMS requirements through the out the organization. PDS ensures its personnel are aware of the relevance and, importance, of their activities and how they contribute to the achievement of the quality objectives through training and other activities. All personnel who manage, perform, and verify work affecting quality, are responsible for maintaining and continually improving the quality system. They are aware of the benefits of conforming to, and the implications of not conforming to the QMS.

The quality manager has the prime responsibility of ensuring the processes needed for the QMS are documented and reporting on the effectiveness and required improvements to top management. The quality manager coordinates, monitors, and audits the system. Effectiveness of the QMS is regularly assessed by way of internal audits and management reviews.

7.4 Communication

Internal communication between personnel in regards to the QMS is achieved through the documentation of the system, training, and meetings between applicable personnel. The Quality Manager is responsible for assuring that the effectiveness of the QMS is understood and communicated throughout the organization.

7.5 Documentation

7.5.1 Documentation

PDS maintains documented information to support the operation of its processes and retains this documentation to instill confidence that the processes are being carried out as planned.

PDS QMS documentation includes:

- Documented statement of PDS Quality Policy and Quality Objectives
- Quality manual
- All required documented procedures, which are implemented and maintained (See Appendix E)
- Documents needed to ensure the effective planning, operation and control of processes
- Documented information and records required by the ISO 9001 / ISO 13485 Standards
- Documents specified by national or regional regulations

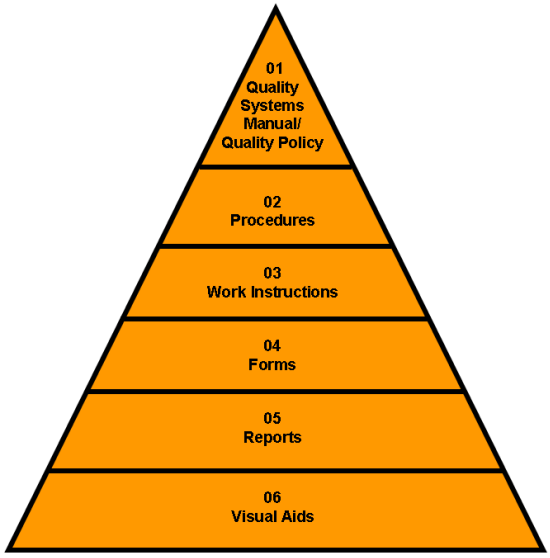


Figure 3 – The documentation structure of the PDS Quality management system

For each type of product, PDS maintains a file which contains documents that define product specifications and quality system requirements. These documents detail the complete manufacturing process and are retained for at least the lifetime of the product as defined by PDS or contract, but not less than the retention period of any resulting record or as specified by relevant regulatory requirements.

The criteria and methods of operation have all been documented within the QMS with reference to information as required. These documents are reviewed for adequacy and approved prior to use by either the original approving function or another designated function with access to pertinent background information. They are controlled, available, readily identifiable, legible, suitable for use, and adequately protected. Changes to, and the current revision, of these documents are identified.

Changes to QMS documents will be evaluated for impact on the QMS and the impact on the product. These changes to QMS documents are also reviewed and approved by either the original approving function or another designated function with access to pertinent background information.

Obsolete documents are identified and controlled to prevent their unintended use. The retention period is defined and documented. See (SX-000-02-003)

Documents of external origin are identified and controlled. Documents are reviewed, updated and re-approved as necessary.

7.5.2 Control of records

Records have been established, are legible, and are maintained to provide evidence of conformity to the QMS and to the processes. Documented procedure (SX-000-02-006) ensures the controls needed for the identification, storage, protection, retrieval, retention time and disposition of these records. Confidential personal information, including health information is controlled and protected. These records are retained for at least the lifetime of the product as defined by PDS or contract, but not less than two years from the date of product release by PDS or as specified by relevant regulatory requirements. PDS does not maintain confidential health records in regards to medical devices.

8.0 Operation

8.1 Planning and of control of product realization

PDS plans product realization requirements through, risk management reviews, controls, approvals, and monitoring to prevent problems which may arise from order processing thru to manufacturing and shipping. These processes are established, planned, and implemented under controlled conditions in a form suitable to PDS's method of operations to ensure product conformity.

Controls on the operations include:

- Work Instructions, indicating the required monitoring and measuring, verification, validation, testing, infrastructure, work environment, traceability, inspection criteria, handling, storage and delivery
- Keeping records of conformity to show evidence that all requirements of the process and products have been met
- Development of process control and plans for key characteristics as required by the customer
- Product standards, representative samples and illustrations as appropriate
- Quality requirements and objectives related to the product
- Determination and provision of resources required

Planned changes to these processes are controlled and the consequences both the positive and the unintended results are reviewed. Documented requirements for risk management have been developed. Risk management efforts are recorded and the records maintained. See (SX-000-02-021)

Risk Management documentation and efforts may include:

- Contract review process and quoting documents
- Management meetings
- (SX-150-04-007) PFMEA
- (SX-150-03-001) New Product Readiness Instruction
- (SX-150-04-014) Risk opportunity matrix
- (SX-150-04-013) PRAP Package

8.2 Requirements for products and service

8.2.1 Customer communication

Customer contact is the main responsibility of program management. Communication between PDS and its customer ensures any enquiries, updates, amendments, additions, order handling, or customer property transfers are handled effectively. See (SX-000-02-010). This will also include any customer complaints, feedback, and assisting in disseminating advisory notices as required.

Advisory notification, statutory and regulatory reporting is handled per PDS Advisory Notices Regulatory Reporting procedure. See (SX-000-02-022)

8.2.2 Determination of requirements related to the product

PDS determines what requirements are needed to fulfill the customer's needs during the RFQ / order processes. These requirements may include:

- Requirements needed for intended use but not stated by the customer, as known
- Delivery and post-delivery requirements
- Statutory, Regulatory and legal requirements as identified.
- Customer specific requirements such as component traceability and workmanship standards.
- Material and manufacturing process requirements
- Any additional requirements determined by PDS
- Training required for the end users of the designed products.

8.2.3 Review of requirements related to product

Prior to commitment of an order to the customer, PDS will review the requirements of the product needed to fulfill the customer's needs during the contract review process. See (SX-000-02-012). Records of this review shall be maintained and any actions required will be kept. To ensure that PDS customers get what they requested on time, traceable, and to the level of quality they expect, contract review procedures ensure that:

- Customer's requirements are unambiguous, clearly defined and documented
- PDS can meet customer product defined requirements
- Changes to customer requirements are resolved, documented and communicable to all persons affected by the changes
- The customer will be contacted to resolve any discrepancy found during the review period, and to define any requirements which are not documented, or have changed from those previously expressed
- Any amendment to the contract will be represented by documents approved by both the customer and PDS
- Requirements specified by the customer for delivery and post-delivery activities
- Statutory, Regulatory and legal requirements can be met
- Additional user training to be provided as identified

Customer requirements will be confirmed prior to order acceptance if the requirements are not clearly defined, ambiguous, or undocumented.

8.3 Design and development

PDS has a design and development process which is established, implemented, and maintained and conforms to ISO9001:2015. PDS does not design or develop medical devices. (See section 4.3)

8.3.1 Planning

PDS prepares a design plan for a new design project, extensive modification to an existing project or possible manufacturing production process. The assigned project manager is responsible for developing the design plan. This plan defines the design and development stages, the reviews, the verifications, and validations that are appropriate to each design and development stage.

The design plan takes into account requirements of internal / external resource needs, extent of customer and other interested party involvement, level of control expected by the customer and other interested parties. It also takes into account the required documentation needed as evidence that the design has met the output criteria and the requirements for the provisions of the service, product, or process.

Responsibilities and authorities for tasks related to a specific design and development project are assigned by the engineering manager and are reflected in the project plan. The design plan will be updated as changes occur and as the design progresses.

The project manager is also responsible for managing the scheduling and planning of the project and the interfaces between all organizations involved. The project manager ensures that the progress of tasks assigned during design review meetings is followed-up and communicated to the design team or appropriate department.

8.3.2 Inputs

Design input requirements that are applicable to a project are identified, documented, and reviewed for adequacy. All inputs shall be resolved until clearly defined, complete, non-conflicting and unambiguous.

These Inputs include:

- Requirements essential for design and development of the product / service
- Applicable statutory and regulatory requirements, standards or codes of practice PDS has committed to implementing
- Functional and performance requirements
- Potential consequences of failures due to nature of the product or service
- Where applicable, information derived from previous similar design

- Internal / external resource needs
- The extent of customer and other interested party involvement, level of control expected by the customer and other interested parties

Documented information regarding the inputs is maintained.

8.3.3 Controls

Design and development is accomplished under controlled conditions. These controls ensure results to be achieved are defined and reviews are conducted to evaluate the ability of the design to meet said requirements. Verification and validation activities are completed to not only ensure the output meets the input requirements, but to also validate the resulting product meets the application or intended use requirements.

If there are any problems which occur during the reviews, verification, or validation necessary actions will be taken. This information will be documented and retained.

8.3.4 Outputs

Design and development output is provided in a form that enables verification and validation activities against the input and is to be approved prior to release. Outputs may be in the form of technical specifications, documents, drawings, bills of materials, etc.

PDS ensures the outputs:

- Meet the input requirements for design and development
- Are adequate for the subsequent processes for the provision of products and services
- Contain or reference project acceptance criteria including monitoring and measuring as appropriate
- Specify the characteristics of the project that are essential for its safe and proper use

8.3.5 Reviews

At the appropriate stages, systematic reviews of the Design and Development are performed in accordance with planned arrangements.

- To evaluate the ability of the results of design and development to meet requirements
- To identify and resolve problem areas

Participants in such reviews include the project manager and representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained.

8.3.6 Verifications

Design and development verification confirms, by objective review, that the specified design and development outputs have met the design and development input requirements. Records of the results of the verifications and any necessary actions are maintained.

8.3.7 Validations

Design and Development validation is performed in accordance with planned arrangements to ensure that the resulting project is capable of meeting the requirements for the specified application or intended use, where known. Whenever practicable, validation is completed before the delivery, implementation, or commissioning of the project. Records of the results of validation and any necessary actions are maintained.

8.3.7 Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified, and validated, as appropriate before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts already provided/ delivered. Records of the results of the review of changes and any necessary actions are maintained.

8.4 Control of externally provided processes, products and services

8.4.1 Purchasing process

PDS has documented and controlled the purchasing process. See (SX -000-02-009). This is to ensure that purchased product, services, and externally provided processes conform to specified requirements and do not adversely affect PDS's ability to deliver conforming products. This includes products or services from external providers whose product or service is intended for incorporation into PDS products, are part of a process provided to PDS, or directly provided to the end customer.

The type and extent of control placed on providers is based on:

- The risk level of the supplied product or service meeting PDS and customer needs
- Statutory and regulatory requirements
- Possible effect it may have on the final product
- The effectiveness of the external providers (supplier) current controls
- External providers level of known competency

Externally provided processes remain within the control of the QMS through provider reviews. Providers are selected, evaluated, and re-evaluated through the provider selection and rating process. These reviews take into account both the controls placed on the provider and the resulting output, thus allowing PDS to verify the effectiveness of the controls applied and to take action when needed. A list of approved providers including evaluations and any actions required from these evaluations is maintained.

The approved external providers (supplier) list will be prepared on results contained from one or more of the following sources:

- New provider reviews
- Questionnaires and audits
- Previously demonstrated quality capability
- Pricing
- On-time deliveries
- Customer requirements
- Corrective action requests and Non-conforming material

8.4.2 Purchasing information

Requirements for externally provided purchased product or services will be reviewed for adequacy prior to communication to the provider. Purchasing documentation to provider will clearly describe the specifications and approval requirements of the material or service ordered including the following:

- Requirements for approval of product , processes, services, methods and equipment
- The requirements for approval of the release of products and services
- Inspection requirements, traceability, or certification of conformity requirements
- External providers required interactions with PDS
- Statutory, regulatory, quality system requirements
- The amount of monitoring and control of the providers performance to be applied
- Written agreement to notify PDS of any anomalies, changes in the process being used which may affect the ability of the purchased product to meet specified requirements
- Verification or validation activities PDS or its customer intends to perform at providers premises
- Competence and requirements for qualification of personnel

Traceability records are maintained to the extent required by customer or regulatory requirements.

8.4.3 Verification of purchased products

Externally provided processes, services, and products received at PDS will be verified in accordance with inspection procedures to ensure provider has met requirements. The amount and type of verification will be based on the provider evaluations and the on the associated risk level of the purchased product.

These may include:

- Records to support the quality of the product from the external providers (supplier), (i.e.: C of C, Test Reports, SPC charts etc.).
- Records to ensure product purchased meets specified purchasing requirements.
- Inspection of the product upon receipt.
- Customer feedback

If verification is to be completed at the external providers (supplier) premises this information will be included on the purchasing documentation. Records of verification will be maintained per records procedure dictates.

When PDS becomes aware of any external providers (supplier) changes in purchased product, PDS will determine if the change(s) have an effect on the product realization process or on the product.

8.5 Production and service provision

8.5.1 Control of production and service provision

To ensure products meet output requirements, production and service provisions at PDS are planned, completed, and monitored under controlled conditions.

These controls include:

- Documented procedures for the control of production
- Documented information describing characteristics, activities and expected results
- Documented product requirements, reference materials and measurement procedures
- Suitable, maintained, available, and controlled monitoring and measuring equipment
- Monitoring and measuring of product characteristics at defined stages verify output requirements have been met
- Controlled infrastructure and environment
- Appointment of competent, trained persons
- Defined release, delivery, and post-delivery activity requirements
- Implementation of actions to prevent human error
- Controlled, implemented, and maintained labeling and packaging requirements
- Removal of manufacturing process agents used during manufacturing as applicable

8.5.1.1 Servicing

Servicing activities are limited to return repairs of assembly level parts as per ISO13845:2016. PDS has documented procedures, work instructions and other required information for completing and verifying repair services to ensure they meet specified requirements. See (SX -000-02-015). Servicing of these repairs includes determining if entry into the complaint system is required, and if input into the improvement process is required.

8.5.1.2 Installation

PDS utilizes external service suppliers for installation activities when required for its manufactured products. These service suppliers are incorporated in the external providers (supplier) rating and approval system. Records of the installations and verification activities are maintained. PDS does not provide installation activities for medical devices. (See section 4.3)

8.5.1.3 Validation of processes

PDS validates assembly processes that the output cannot be verified by monitoring or measuring.

Validation procedures include:

- Defining the criteria for review and approval of such processes
- Approval of equipment and qualification of personnel
- Use of defined specific methods and procedures
- Statistical techniques where applicable
- Record requirements
- Revalidation and criteria
- Approvals for changes in the processes

Records of the results and conclusions including action required to be taken are maintained.

8.5.2 Identification and Traceability

Documented procedure (SX -000-02-018) ensures PDS identifies parts and materials for use in the manufacture of products during all phases of product realization. Purchased material used in the manufacture of products will be traceable back to this source of supply.

Assembly traceability and product realization status, in regards to monitoring and measuring, is completed with documented procedure (SX -000-02-018). This procedure ensures the unique identification of the product is controlled, and that only product that has passed the required inspection and tests is released. If unique identification traceability is a requirement of the product by customer contract or regulatory requirement, records of this traceability will be maintained.

A documented procedure is established to ensure products returned will be identified upon receipt and segregated from production units. These will have an identification (RMA) number associated with them prior to receiving. This procedure is documented and maintained. See (SX -000-02-015).

PDS does not currently produce any active implantable or implantable devices. See (See section 4.3)

8.5.3 Customer or external provider property

All customer or external provider supplied material (consignment material) shall be identified, verified, protected, and safeguarded, from unauthorized use or disposition. Consignment material may include test fixtures, tooling, drawings, electronic files, parts, raw materials, intellectual property and confidential health or personal information. Customer or external provider owned material shall be examined, upon receipt for:

- Damage
- Quantity
- Conformity

Any discrepancy, damage, lost, or otherwise found unsuitable item(s) shall be reported to the customer or external provider whom supplied the materials through program management and records will be maintained.

Proper precautions will also be taken to assure that no damage or deterioration occurs during handling or storage.

8.5.4 Preservation of Product

Through documented procedures PDS shall maintain product integrity of all production materials and outputs during internal processing and delivery. See (SX-000-02-013). Product integrity is protected from alteration, contamination and damage when exposed to expected conditions and hazards during processing, storage, handling and distribution.

Some of the methods of product preservation and product integrity protection used by PDS include:

Identification

- Examples of product, packaging and master carton marking as required or needed
- Serial numbers
- Expiration date, controlling limited shelf life materials
- Regulatory marking requirements
- Traceability

Handling

- Appropriate containers, pallets or work platforms will be used to protect the product
- Operating lift trucks, trucks, loaders, and other vehicles in a safe manner to minimize damages
- Any goods, which are kept for extended periods of time, will be checked for shelf life damage

Packaging

- PDS will package providing appropriate protection during shipping, or utilize customer-supplied instructions when provided
- Custom packaging solutions
- Documented procedures for packaging when normal procedures will not sufficiently protect

Storage

- PDS provides adequate space and facilities
- Ensures cleanliness
- Maintains appropriate temperature and humidity as necessary to prevent premature degradation.
- Provides for appropriate identification marking and traceability

Documented procedures / work instructions are implemented and maintained for the control of limited shelf life materials and for materials requiring special storage and handling. These storage conditions shall be controlled and records maintained.

8.5.5 Post-delivery activities

The amount of activity in regards to post-delivery activities requirements takes into account a variety of things. Any statutory and regulatory requirements, customer feedback loops, customer requirements, the nature, use and intended lifecycle of the products services and the potential for undesired consequences associated with its products.

8.5.6 Change control

PDS Controls changes to ensure continued product conformity. Changes are reviewed prior to implementation and records of the reviews are maintained. These documented reviews include the person authorizing the change and actions necessary arising from the review.

8.6 Release of products and services

Product and service arrangements are verified at appropriate stages to ensure that requirements have been met. Product or services release will not proceed until the planned arrangements have been met unless approved by a relevant authority and the customer as applicable.

Documented evidence of the release of products or service will be maintained including evidence of conformity with the acceptance criteria and traceability to the person authorizing the release. Each product work order has a record of traceability that is maintained describing the amount manufactured and the amount approved for distribution. This record is verified and approved prior to the finalizing of the record.

8.7 Control of non-conforming outputs

8.7.1 General

Non-conforming output can be defined as any material or component, assembly, or service output which does not conform to specifications, engineering drawings, customer requirements or associated quality standards.

Non-conforming outputs are identified, documented, segregated, evaluated, dispositioned and controlled to prevent unintentional usage or delivery. Procedures are established and maintained. See (SX-000-02-005).

8.7.2 Actions taken prior to release

Actions taken are based on the nature of the non-conformity and its effect on the product or service. Non-conforming output is dealt with in one or more of the following ways.

- Correction and corrective action
- Informing the customer or a third party if they are responsible
- Segregation, containment, or suspension of provision of products and service
- Obtaining authorization to accept by concession
- Taking action to preclude its original intended use or application

PDS policy is to identify, document, and prevent re-occurrence of non-conformances. Non-conforming reports give indication where and when corrective action is required to prevent re-occurrence.

All reworked material requiring a non-conforming report (rework which restores the functional capability of a non-conforming article in a manner that precludes compliance of the article with applicable drawings or specifications) will be reviewed by a Material Review Board (MRB) consisting of: Quality Manager, Production Manager, Process Engineering or their pre-designated representative(s), and one or more of them shall provide authorized disposition. When necessary for the disposition of non-conforming outputs, the customer is contacted and concessions obtained. The disposition decision may include:

- Return to vendor / provider
- Return to stock
- Rework
- Repair
- Use as is
- Scrap
- Revision change

Non-conforming material may be used when dictated by contract. The customer representative will be contacted to gain approval and allowance for the non-conformity. This approval can only occur if all regulatory requirements have been met. The person(s) authorizing this concession is maintained.

8.7.3 Actions taken post delivery

When non-conforming product is detected after delivery, the potential effects will be reviewed and appropriate action will be taken. Advisory Notices and Regulatory Reporting procedure details the instructions for issuance of advisory notices per regulatory requirements as applicable if the non-conformity was detected after delivery. See (SX-000-02-022). This process can be put in effect at any time and the actions relating to the issuance are recorded.

8.7.4 Rework

Rework processes shall be documented in a work instruction which has undergone the same approval process as the original work instruction. Prior to authorization and approval of the work instruction, a determination of adverse effects of the rework shall be made and documented. Non-conforming product is re-inspected and re-verified in accordance with written procedures to ensure conformity to specifications and

regulatory requirements. Documented information is retained in regards to the description of the no-conformity, the action(s) taken, concessions obtained and the authority deciding the correct action to take.

9.0 Performance evaluation

9.1 Monitoring, measurement analysis and evaluation

PDS monitors and measures throughout the product realization processes. The methods for monitoring, measurement analysis and evaluation are determined to ensure valid results. These methods are carried out at appropriate stages and corrective actions shall be taken when planned results are not achieved.

9.1.1 Monitoring, measurement, analysis and evaluation

Quality system processes at PDS will be monitored, measured, analyzed and evaluated. These activities are to demonstrate the ability of the process to achieve planned results. They are also to demonstrate conformity of the QMS and that it is maintained and effective.

Quality management system monitoring and measuring includes:

- Customer satisfaction and feedback
- Quality management system (Internal and external audits)
- Process and product statistical techniques
- Continual improvement reviews
- Corrective and preventive action
- Control of non-conformities
- External providers
- Service reports and RMA evaluations

To ensure product requirements have been met, PDS monitors, measures, analyzes and evaluates product characteristics at appropriate stages during the product realization process. This is completed using documented procedures. These actions include:

- Incoming materials; Procedures for inspection and verification
- In-process product; Procedures for identifying and inspecting products
- Testing of product; Procedures for functional or in circuit testing
- Finished product; Procedures that ensure that inspection and tests are completed and shippable product conforms to requirements

The identity of personnel performing these activities will be recorded and maintained.

If monitoring and measuring indicate quality goals or objectives are not met, action is taken. Actions may include issuing corrective action, generating process improvements, additional monitoring, and additional training among others. Many times these actions occur in real time and are recorded through assembly documentation updates or other process changes.

9.1.2 Customer Satisfaction

PDS will review customer satisfaction records to ensure that customer requirements have been met. This information is incorporated into the management reviews, corrective / preventative action system.

Methods of obtaining and using customer satisfaction and/or dissatisfaction information may include the following:

- Customer complaints
- Customer returns
- Questionnaires and surveys
- Direct customer communication
- Customer visits / audits
- Corrective actions

A documented procedure (SX -000-02-010) has been established and is maintained for customer feedback. This ensures that PDS has a method of early warnings to input into preventative, corrective action, and risk processes. Additional feedback includes production activities as well as post production.

If national or regional regulations are identified that requires PDS to gain experience from the post production phase it will be included in the feedback system.

9.1.3 Complaint Handling

PDS Procedure (SX -000-02-010) ensures complaint handling is completed in a timely manner. The program manager or quality assurance manager receives and process the complaint. They record, evaluate, and determine if the complaint is required to be logged into the feedback system. Investigation will occur and regulatory authorities notified as applicable.

Justification is indicating for any complaint not requiring investigation. Correction and corrective actions are recorded and maintained on the complaint. If investigation determines sources outside of PDS contributed to the complaint the external source will be notified and information transferred for corrective actions.

9.1.4 Regulatory Reporting

If applicable regulatory requirements require notification of complaints that meet reporting criteria of adverse events or issuance of advisory notices the PDS Advisory Notices Regulatory Reporting procedure includes this process. See (SX-000-02-022)

9.2 Internal audits

Internal audits will be used with the goal of continual improvement of PDS's QMS. These ensure the QMS conforms to planned arrangements, applicable national standards, and that it is implemented and maintained. The audit intervals, criteria, scope, and methods are defined. See (SX -000-02-011)

Audits will be carried out against documented procedures and regulatory requirements. They are completed minimally on an annual schedule based on the importance or the processes, changes affecting PDS, and the results of previous audits.

Auditors are trained and will be selected independent of the area to be audited to ensure objectivity and impartiality.

Corrective actions noted during previous audits are verified for completion and effectiveness. Managers or supervisors of the department being audited review the results and ensure that required actions from audit results are completed without undue delay. Follow-up corrective action and results of these audits will be documented and reported. Records of audits will be maintained.

9.3 Management review

PDS's executive management reviews the QMS at least once a year. The purpose of this review is to ensure the effectiveness and continuing suitability, adequacy, of the QMS to meet the requirements of ISO standards and PDS's Quality Policy, objectives, and strategic direction.

This review includes assessing opportunities for improvement and the need for changes to the QMS. Top management is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded. See (SX-000-02-004)

9.3.1 Input

Inputs have been identified as part of the agenda set for the management review. At a minimum these inputs shall include:

- Quality policy/quality objectives
- Follow up actions from previous management reviews
- Changes that could affect the QMS
- Opportunities for improvement
- Results of audits
- Feedback

- Corrective/preventative actions
- Complaint handling
- Process performance and product conformity
- Status of preventative and corrective actions
- New or revised regulatory requirements/ regulatory reporting
- Internal / External issues relevant to the QMS
- Effectiveness of actions to address risk and opportunities

9.3.2 Outputs

The output from the management review is recorded in the form of minutes and a list of action items. At a minimum the list of action items shows:

- Any changes, improvements, or opportunities found to maintain adequacy or improve the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs
- Changes needed to respond to new or revised regulatory requirements

10.0 Improvement

PDS has a documented system in place, which uses a planned approach to maintaining processes, solving problems, and implementing continual improvements to meet customer requirements and enhance customer satisfaction. See (SX -000-02-002). PDS determines and selects opportunities for improvements and implements the actions necessary.

Actions may include improving products and services to meet requirements current and future. Correcting, preventing or reducing undesired effects, and improving the performance of the QMS. PDS utilizes data to make improvements and to maintain to the quality systems.

This data may include:

- Result of internal / external audits
- Corrective / preventative actions
- Management review
- Analysis of data
- Quality policy
- Quality objectives
- Customer complaints / surveys

10.1 Corrective action and non-conformity

PDS has a documented procedure, for reviewing, determining cause, evaluating need for action, planning, documenting, and taking corrective action to eliminate the causes of non-conformance and prevent re-occurrence. See (SX -000-02-008). This includes evaluating the need for action by analyzing the non-conformity, determining the cause, and reviewing if similar non-conformances may exist. The risks and opportunities found during planning may be updated as a result of the corrective action.

The corrective actions taken are appropriate to the effects of the non-conformity. Determination of the corrective action is made, recorded and controls are incorporated ensure that the corrective action is implemented and effective.

Follow-up on the effectiveness of actions taken will be completed and documented upon full root cause analysis and implementation of the corrective action. The quality assurance function has the main responsibility for the verification unless stated otherwise in the corrective action request.

Customer complaints are documented per the customer communication procedure (SX -000-02-010). If the complaint is determined to be the result of a component manufacturer or sub-contractor the corrective action shall be obtained from them through Purchasing, Program Management and / or Quality Assurance functions.

If national or regional regulation requires notification and issuance of advisory notices this is handled per the Advisory Notices Regulatory Reporting procedure. See (SX-000-02-022)

10.2 Preventive Action

PDS will identify areas of potential improvements, evaluate the need, determine and implement actions to be taken to prevent non-conformance. Potential improvements may be identified during internal audits, management reviews, risk/opportunity reviews, and through other continual process improvement and preventive action processes.

Preventative actions taken shall be appropriate to the effects of the potential non-conformity. See procedure (SX 000-02-002). The potential non-conformity, its cause, and the need for action will be determined. The action will be planned, documented and reviewed accordingly to ensure it does not adversely affect the product. The effectiveness of the action(s) put into place will be verified.

Records of preventative action investigations, implementations and reviews of effectiveness will be recorded.

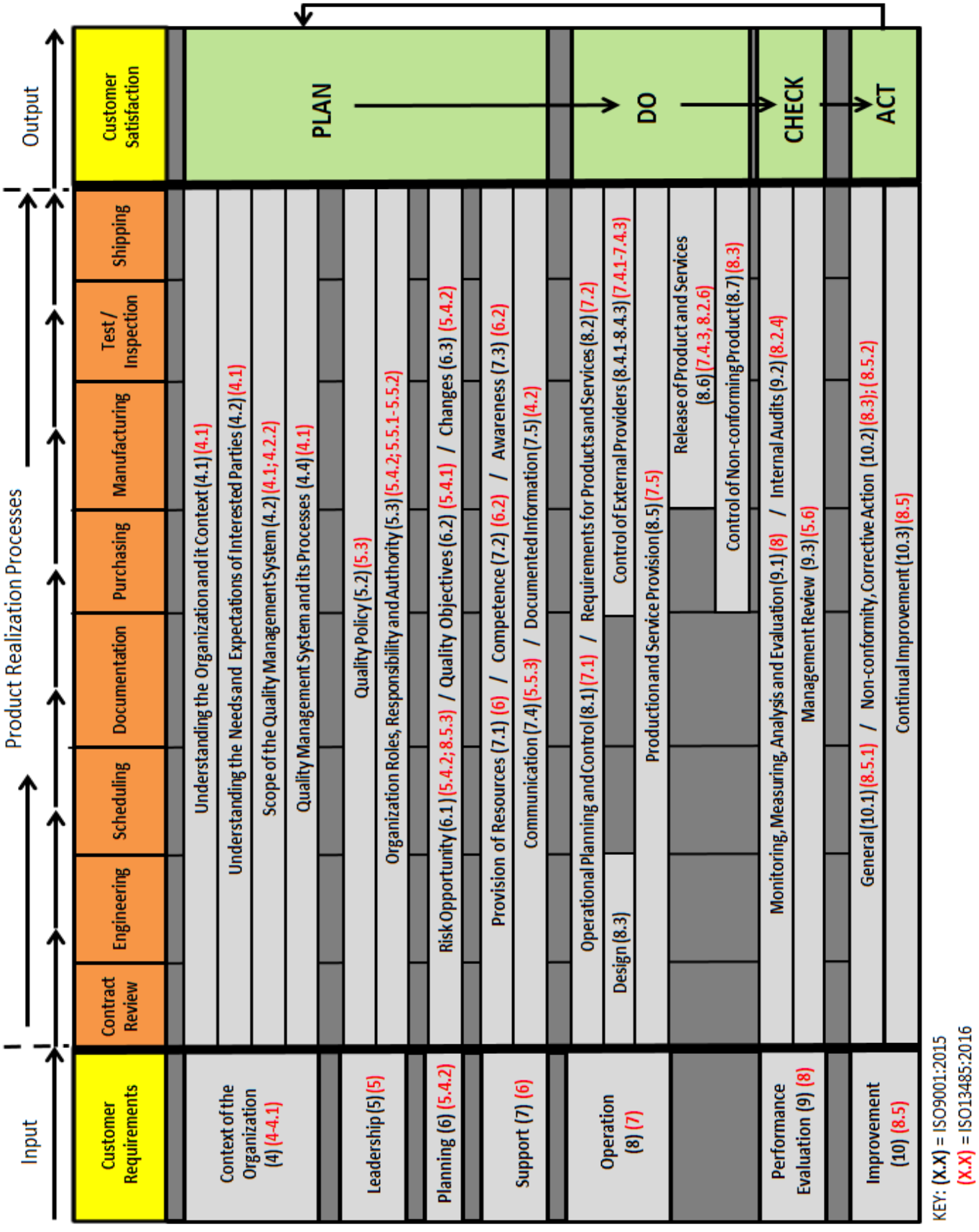
Appendix A: Internal and External Issues Table:

Internal issues that could affect PDS products; services; interested parties	***External*** issues that could affect PDS products; services; interested parties
Organization:	**Competitors / Economic shift:**
• Structure • Management's abilities • Business continuity considerations • Strategic Direction • Decision making processes • Relationships with interested parties – Stake holders • Standards, guidelines and models adopted	• Overall competition • Technology advances • Competitors cease • Overall economic climate in the country • Standardization and certification within the industry
Staff:	**External Providers (suppliers):**
• Culture within PDS; Staff morale • Effective internal communication • Stability of workforce; staff retention • Knowledge; General competence • Motivation of workforce • Potential conflicts; Processes for resolving conflicts • Legislation, e.g. employment of non-nationals	• Availability of raw materials • Quality / Performance • On time deliveries • Regulatory Compliance • Counterfeit protection programs • Changes to Process/Location
Resources:	**Regulation:**
• Facilities / equipment • Capabilities / technologies • Availability of reliable, qualified, competent workforce • Database systems • Working hours / availability • External providers – supplier competence / availability	• Legislation, employment, data protection, health and safety, environmental requirements • Environmental requirements affecting products and service • Workforce culture within the surrounding area
Customers:	**Customers:**
• Contractual arrangements with customer • Solvency of customers • Expansion of customer base • Perceptions/values of PDS interested parties	• Relationships • Perceptions/values • External inspections/audits • Customer demographic

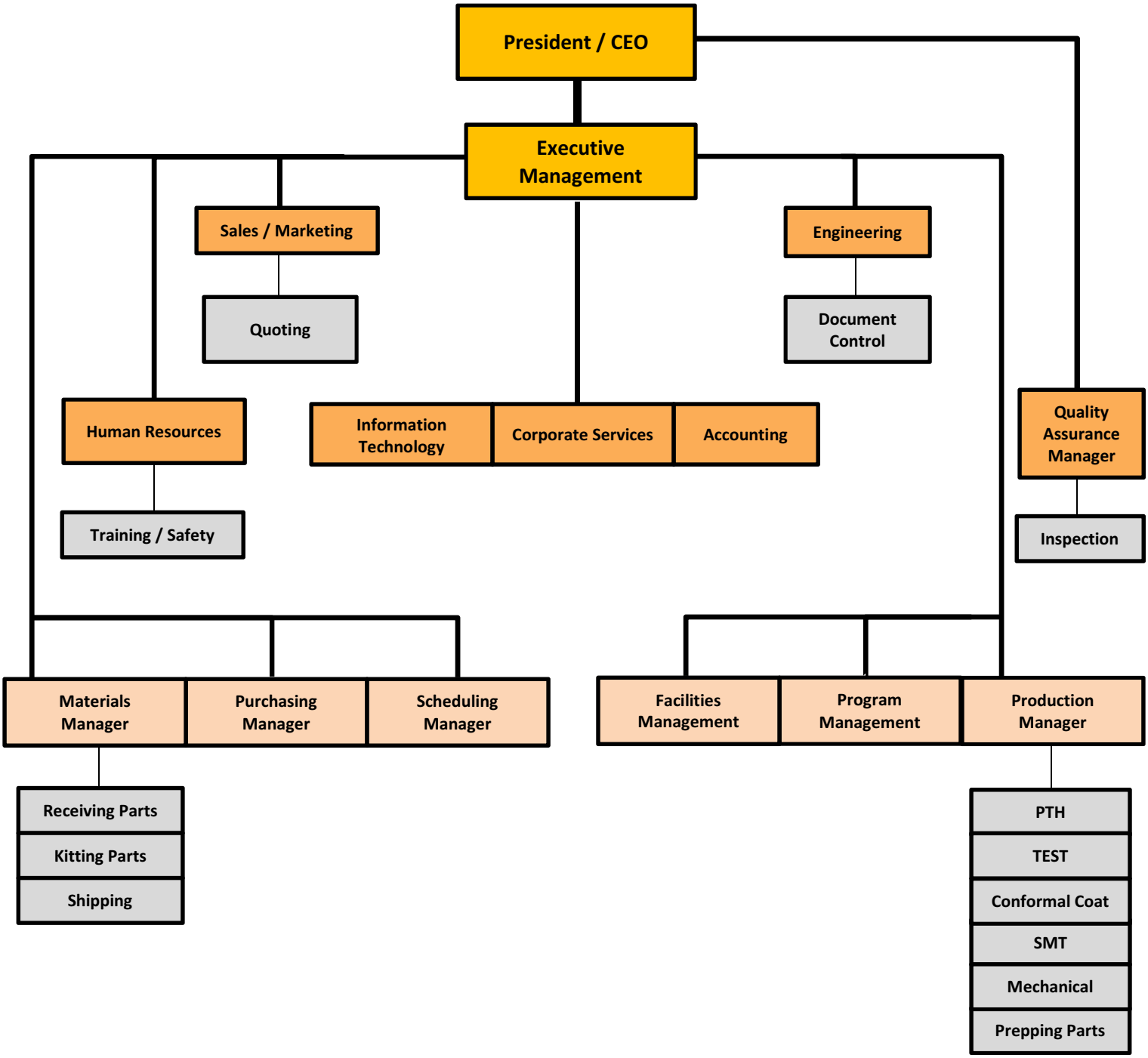
Appendix B: List of Interested Parties / Stake Holders:

Interested Parties	Requirements	Monitoring and Review Mechanism
Executive Board / Partners	Legal compliance	Management Review
Local residents	Local employment Good reputable employer	HR Reviews Management Review
Government agencies	Identification, understanding, updating and maintenance of applicable statutory and regulatory requirements within the Management System	Management Review
Customers /clients	High quality On time Quick response Expectations for design innovation	Customer Feedback Methods Quality Goals Measurements Program Management Engineering
Employees	Professional development Employment security Good employee working relationships	HR Reviews Management Review HR Reviews
External providers; suppliers	Clear, unambiguous contracts and scope of work Good working relationship High quality products/services	Contract Review Process Program Management Quality Goals

Appendix C: QMS Process Sequence and Interaction



Appendix D: Organization Chart:



Appendix E: Quality Management Top Level System Procedures:

NUMBER	TITLE
(SX-000-02-001)	Calibration
(SX-000-02-002)	Continual Improvement/Preventative Action
(SX-000-02-003)	Documentation
(SX-000-02-004)	Management Review
(SX-000-02-005)	Control of Non-Conforming Product
(SX-000-02-006)	Control of Records
(SX-000-02-007)	Training
(SX-000-02-008)	Corrective Action
(SX-000-02-009)	Purchasing
(SX-000-02-010)	Customer Communication
(SX-000-02-011)	Internal Audits
(SX-000-02-012)	Contract Review
(SX-000-02-013)	Materials Preservation Storage and Delivery
(SX-000-02-014)	Analysis of Data
(SX-000-02-015)	Returned Material Authorization
(SX-000-02-016)	Customer Supplied Material
(SX-000-02-017)	Radiation Protection Program
(SX-000-02-018)	Product Identification and Traceability
(SX-000-02-019)	Software Validation
(SX-000-02-020)	Design and Development
(SX-000-02-021)	Risk and Opportunity Management
(SX-000-02-022)	Advisory Notices Regulatory Reporting

Appendix F: Facilities, and Certifications list:

Manufacturing Division
1760 S. Dimensions Terrace
Homosassa, FL 34448
352-795-0101
352-564-0772 (Fax)
ISO 9001 / ISO13485

Manufacturing Division
430 N Suncoast Blvd
Crystal River FL, 34429
352-795-0101
352-564-0772 (Fax)
ISO 9001 / ISO13485

Table 1: Correspondence between ISO9001:2015; ISO13485:2016; and PDS Quality System

Clause in ISO 9001:2015	Clause in ISO 13485:2016	Sibex Quality manual
1 Scope	1 Scope	
4 Context of the organization	4 Quality management system	4.0 Organization and context
4.1 Understanding the organization and its context	4.1 General requirements	4.1 PDS organization and its context
4.2 Understanding the needs and expectations of interested parties	4.1 General requirements	4.2 PDS interested parties and their requirements.
4.3 Determining the scope of the quality management system	4.1 General requirements	4.3 Scope of the PDS quality management system (QMS)
	4.2.2 Quality manual	4.3 Scope of the PDS quality management system (QMS)
4.4 Quality management system and its processes	4.1 General requirements	4.4 PDS quality management systems and it processes
5 Leadership	5 Management responsibility	5.0 Leadership
5.1 Leadership and commitment	5.1 Management commitment	5.1 Leadership and commitment
5.1.1 General	5.1 Management commitment	5.1 Leadership and commitment
5.1.2 Customer focus	5.2 Customer focus	5.1 Leadership and commitment
5.2 Policy	5.3 Quality policy	5.2 Policy
5.2.1 Establishing the quality policy	5.3 Quality policy	5.2 Policy
5.2.2 Communicating the quality policy	5.3 Quality policy	5.2 Policy
5.3 Organizational roles, responsibilities and authorities	5.4.2 Quality management system planning	5.2 Policy
	5.5.1 Responsibility and authority	5.2 Policy
	5.5.2 Management representative	7.3 Awareness
6 Planning	5.4.2 Quality management system planning	6.0 Planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning	6.1 Risk and opportunity
	8.5.3 Preventive action	10.2 Preventive Action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives	6.2 Quality objectives and planning
6.3 Planning of changes	5.4.2 Quality management system planning	6.3 Planning of changes
7 Support	6 Resource management	7.0 Support
7.1 Resources	6 Resource management	7.1 Resources
7.1.1 General	6.1 Provision of resources	7.1 Resources
7.1.2 People	6.2 Human resources	7.1 Resources
7.1.3 Infrastructure	6.3 Infrastructure	7.1.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4.1 Work environment	7.1.4 Work Environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment	7.1.1 Monitoring and measuring resources
7.1.5.1 General	7.6 Control of monitoring and measuring equipment	7.1.1 Monitoring and measuring resources
7.1.5.2 Measurement traceability	7.6 Control of monitoring and measuring equipment	7.1.1 Monitoring and measuring resources
7.1.6 Organizational knowledge	6.2 Human resources	7.1.2 Organizational knowledge as a resource
7.2 Competence	6.2 Human resources	7.2 Competence
7.3 Awareness	6.2 Human resources	7.3 Awareness
7.4 Communication	5.5.3 Internal communication	7.4 Communication
7.5 Documented information	4.2 Documentation requirements	7.5 Documentation
7.5.1 General	4.2.1 General	7.5 Documentation

7.5.2 Creating and updating	4.2.4 Control of documents	7.5 Documentation
	4.2.5 Control of records	7.5.2 Control of records
Clause in ISO 9001:2015	**Clause in ISO 13485:2016**	**Sibex Quality manual**
7.5.3 Control of documented Information	4.2.3 Medical device file	7.5.1 Documentation
	4.2.4 Control of documents	7.5 Documentation
	4.2.5 Control of records	7.5.2 Control of records
	7.3.10 Design and development files	7.5.2 Control of records
8 Operation	7 Product realization	8.0 Operation
8.1 Operational planning and control	7.1 Planning of product realization	8.1 Planning and of control of product realization
8.2 Requirements for products and services	7.2 Customer-related processes	8.2 Requirements for products and service
8.2.1 Customer communication	7.2.3 Communication	8.2.1 Customer communication
8.2.2 Determining the requirements for products and services	7.2.1 Determination of requirements related to product	8.2.2 Determination of requirements related to the product
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to product	8.2.3 Review of requirements related to product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to product	8.2.3 Review of requirements related to product
8.3 Design and development of products and services	7.3 Design and development	8.3 Design and development (N/A ISO13485)
8.3.1 General	7.3.1 General	8.3 Design and development (N/A ISO13485)
8.3.2 Design and development planning	7.3.2 Design and development planning	8.3.1 Planning (N/A ISO13485)
8.3.3 Design and development inputs	7.3.3 Design and development inputs	8.3.2 Inputs (N/A ISO13485)
8.3.4 Design and development controls	7.3.5 Design and development review	8.3.3 Controls (N/A ISO13485)
	7.3.6 Design and development verification	8.3.6 Verifications (N/A ISO13485)
	7.3.7 Design and development validation	8.3.7 Validations (N/A ISO13485)
	7.3.8 Design and development transfer	8.3.4 Outputs (N/A ISO13485)
8.3.5 Design and development outputs	7.3.4 Design and development outputs	8.3.4 Outputs (N/A ISO13485)
8.3.6 Design and development changes	7.3.9 Control of design and development changes	8.3.7 Changes (N/A ISO13485)
8.4 Control of externally provided processes, products and services	7.4.1 Purchasing process	8.4 Control of externally provided processes, products and services
	7.4.1 Purchasing process	8.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process	8.4.1 Purchasing process
8.4.2 Type and extent of control	7.4.1 Purchasing process	8.4.1 Purchasing process
	7.4.1 Purchasing process	8.4.1 Purchasing process
	7.4.3 Verification of purchased product	8.4.3 Verification of purchased products
8.4.3 Information for external providers	7.4.2 Purchasing information	8.4.2 Purchasing information
	7.4.3 Verification of purchased product	8.4.3 Verification of purchased products
8.5 Production and service provision	7.5 Production and service provision	8.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
	7.5.6 Validation of processes for production and service provision	8.5.1.3 Validation of processes
8.5.2 Identification and traceability	7.5.8 Identification	8.5.2 Identification and Traceability
	7.5.9 Traceability	8.5.2 Identification and Traceability
8.5.3 Property belonging to customers or external providers	7.5.10 Customer property	8.5.3 Customer external provider property
8.5.4 Preservation	7.5.11 Preservation of product	8.5.4 Preservation of Product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision	8.5.5 Post-delivery activities

	7.5.3 Installation activities	8.5.1.2 Installation
	7.5.4 Servicing activities	8.5.1.1 Servicing
	8.2.2 Complaint handling	9.1.3 Complaint Handling
	8.2.3 Reporting to regulatory authorities	9.1.4 Regulatory Reporting
	8.3.3 Actions in response to nonconforming product detected after delivery	8.7.3 Actions taken post delivery
8.5.6 Control of changes	7.3.9 Control of design and development changes	8.5.6 Change control
8.6 Release of products and services	7.4.3 Verification of purchased product	8.6 Release of products and services
	8.2.6 Monitoring and measurement of product	
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product	8.7 Control of non-conforming outputs
9 Performance evaluation	8 Measurement, analysis and improvement	9.0 Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement	9.1 Monitoring, measurement analysis and evaluation
9.1.1 General	8.1 General	9.1 Monitoring, measurement analysis and evaluation
	8.2.5 Monitoring and measurement of processes	9.1.1 Monitoring, measurement, analysis and evaluation
	8.2.6 Monitoring and measurement of product	9.1.1 Monitoring, measurement, analysis and evaluation
9.1.2 Customer satisfaction	7.2.3 Communication	9.1.2 Customer Satisfaction
	8.2.1 Feedback	9.1.2 Customer Satisfaction
	8.2.2 Complaint handling	9.1.3 Complaint Handling / 9.1.4 Regulatory Reporting
9.1.3 Analysis and evaluation	8.4 Analysis of data	9.1.1 Monitoring, measurement, analysis and evaluation
9.2 Internal audit	8.2.4 Internal audit	9.2 Internal audits
9.3 Management review	5.6 Management review	9.3 Management review
9.3.1 General	5.6.1 General	9.3 Management review
9.3.2 Management review inputs	5.6.2 Review input	9.3.1 Input
9.3.3 Management review outputs	5.6.3 Review output	9.3.2 Outputs
10 Improvement	8.5 Improvement	10.0 Improvement
10.1 General	8.5.1 General	10.0 Improvement
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product	10.1 Corrective action and non-conformity
	8.5.2 Corrective action	10.1 Corrective action and non-conformity
10.3 Continual improvement	5.6.1 General	10.2 Preventive Action
	8.5 Improvement	10.2 Preventive Action