Quality Standards Manual

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Odyssey Electronics, Inc.
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Odyssey Electronics, Inc.
Quality Standards Manual

Rev: 2.9

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1 Quality Manual Revision History

Revision Level	Change Summary	Date
1.0	Origin	11/16/98
1.1	Organizational Chart	10/14/99
1.2	Added the need for statistical techniques; Added procedural references to 1.3 and 2.3	01/04/00
1.3	Organizational Chart; Quality Policy	07/25/00
1.4	Organizational Chart	09/26/01
1.5	Organizational Chart	04/11/02
1.6	Updated to coincide with ISO 9001:2000	02/17/03
1.7	Comprehension issues (4.2.2, 7.1, 7.2.3 & 8.3)	05/30/03
1.8	Organizational Chart; monthly employee meetings (5.5.3)	01/02/04
1.9	January exemption from monthly meetings; Org. Chart	01/21/05
2.0	Organizational Chart	05/21/07
2.1	Organizational Chart	07/23/07
2.2	Organizational Chart	04/30/08
2.3	Organizational Chart	04/27/09
2.4	Organizational Chart; Included VP as possible presence to management review	07/29/09
2.5	Updated to ISO 9001:2008; Organizational Chart	08/09/10
2.6	Upgraded to ISO 13485:2003.	07/20/11
2.7	Upgraded to ISO 13485:2016; Organizational Chart	11/04/17
2.8	Added our scope, our "Process Sequence" and a documentation structure outline.	03/01/19
2.9	Organizational Chart	08/01/22

2 Quality Manual Review and Approval

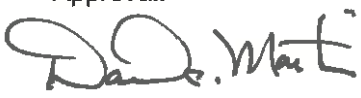
Review:

Laura Henning
Quality Manager

Approval:

Ernest V. Flamont
President

Approval:

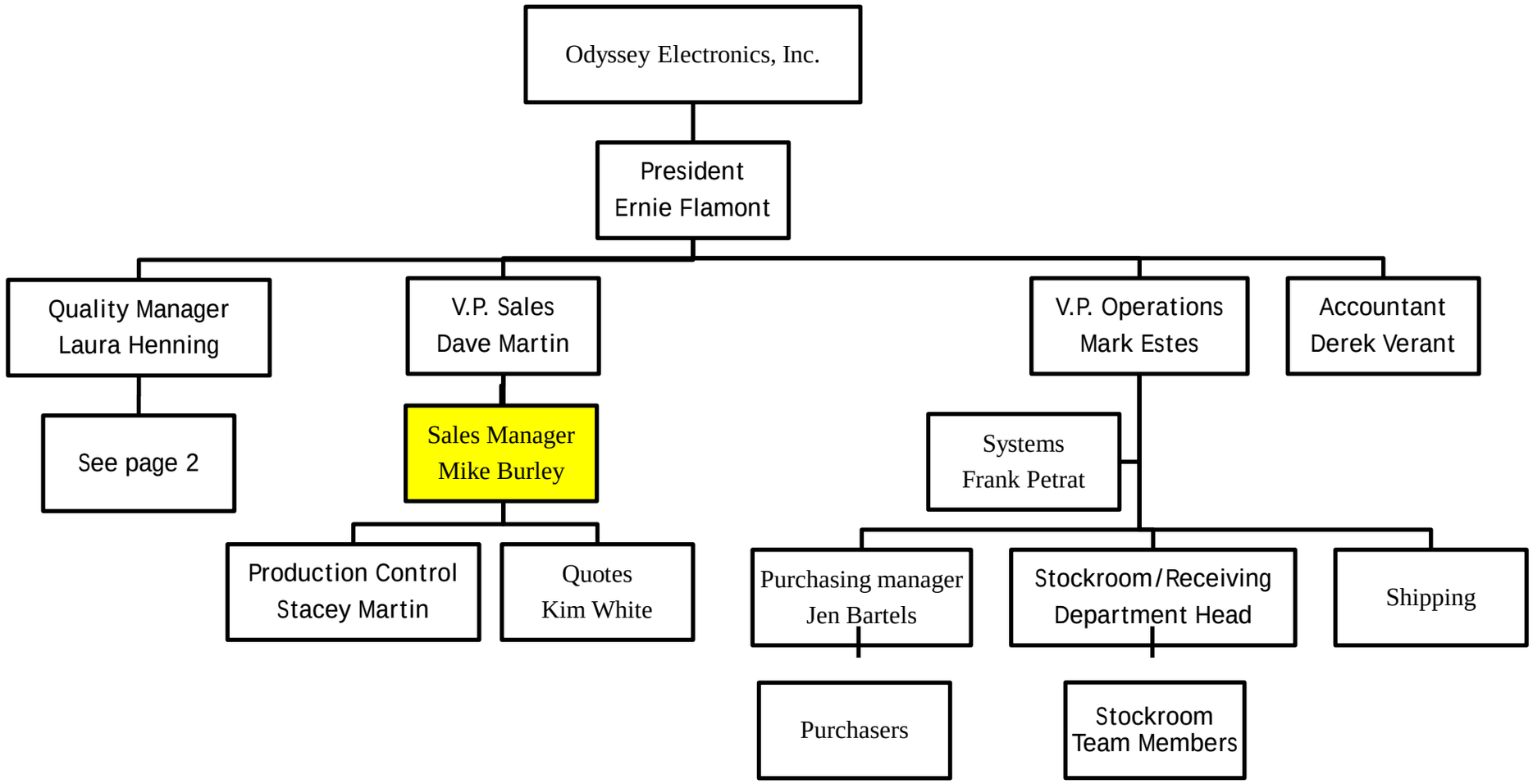


David C. Martin
V. President

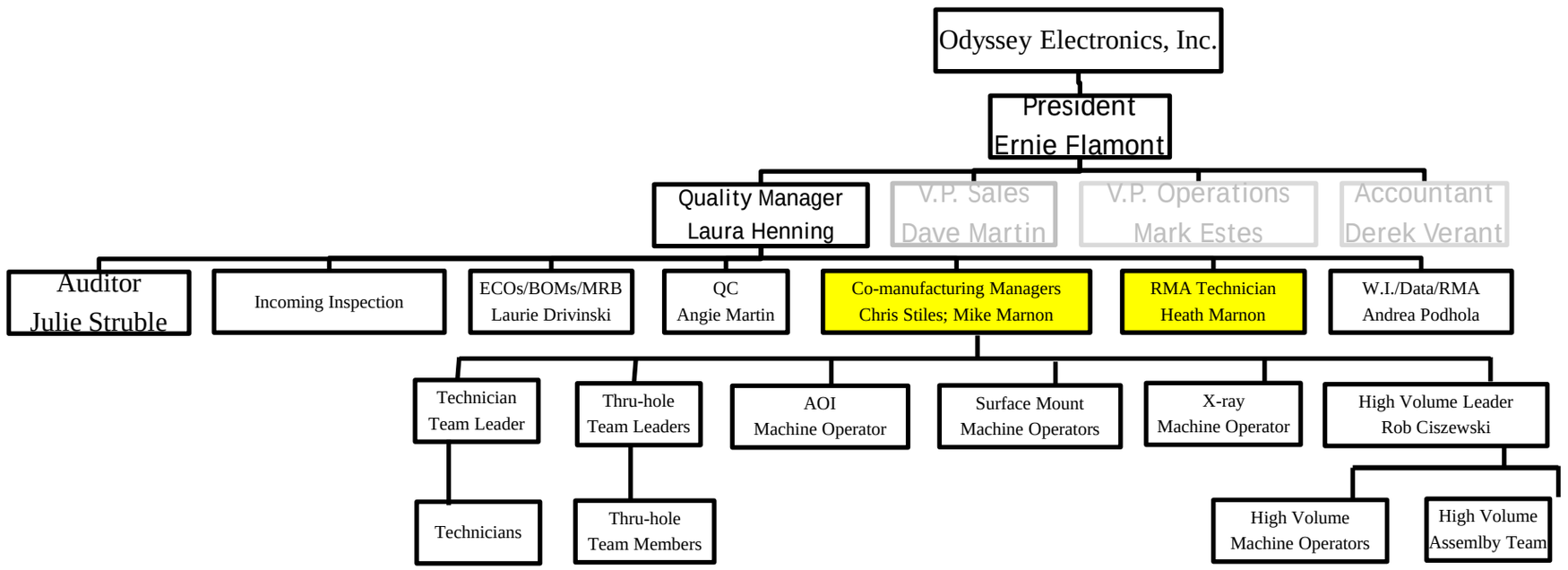
Approval:

Mark E. Estes
V. President

3 Organizational Chart



3 Organizational Chart (Continued)



4 Quality management system

4.1 General requirements

Odyssey Electronics, Inc. has an established, documented, implemented and maintained quality management system and continually improves its effectiveness in accordance with the requirements of the International Standard ISO 13485:2016 and applicable regulatory requirements.

The organization monitors, measures and analyzes processes needed for the quality management system throughout the organization for the continual improvement of these processes in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements.

All changes to these processes are evaluated for their impact on the quality management system and medical devices, and controlled per requirements of ISO 13485:2016 and applicable regulatory requirements.

Control of any outsourced processes is identified within the quality management system.

Computer software used in the quality management system is validated prior to use and after changes, in proportion to the associated risks.

4.2 Documentation requirements

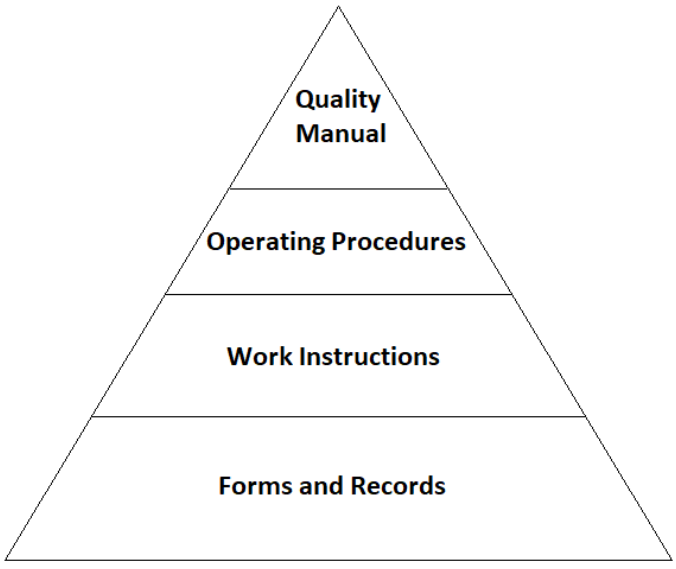
4.2.1 General

The quality management system documentation includes a quality policy with objectives, this quality manual, operating procedures, work instructions and records required by International Standard ISO 13485.

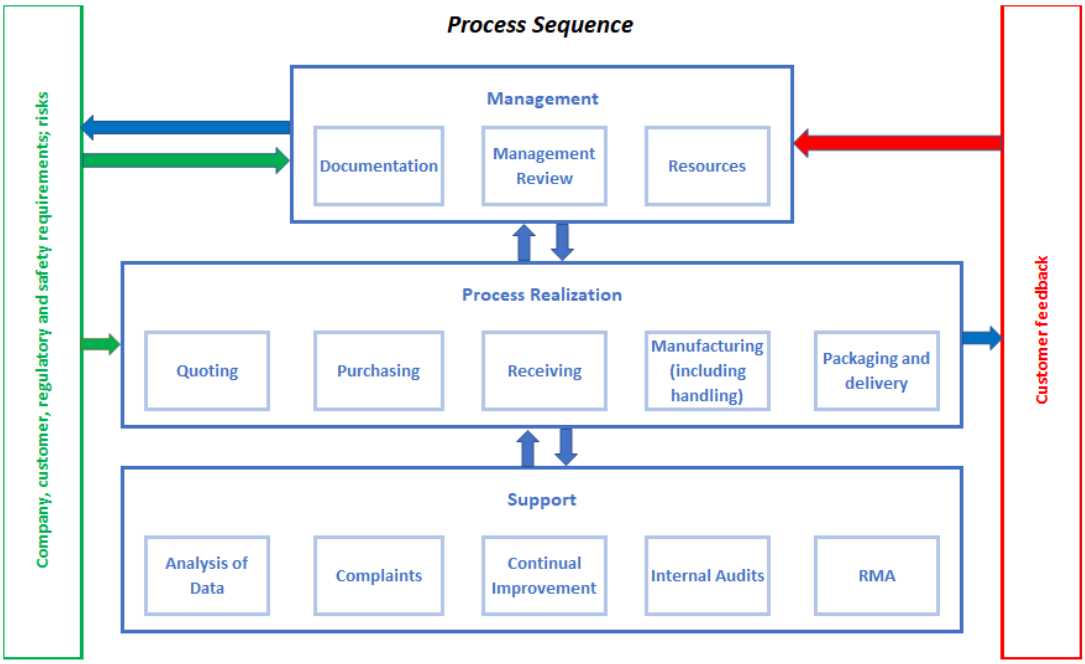
4.2.2 Quality manual

Odyssey Electronics, Inc. is a manufacturer of industrial controls, printed circuit boards assemblies and other electronic assemblies. This quality manual includes any exclusion with justification and references to the operating procedures established for the quality management system.

The documentation outline of the quality management system:



4.2.2 Quality manual (continued)



4.2.3 Medical device file

A file has been established for each assembly containing all pertinent documentation specific to each assembly.

Operating procedure 4.2 (“Documentation Requirements”) defines the period of time copies of all medical device documents are retained.

4.2.4 Control of documents

Documents required by the quality management system are controlled. Records are controlled according to the requirements given in 4.2.4.

Operating procedure 4.2 (“Documentation Requirements”) defines the controls needed to approve, review and update documents for adequacy prior to issue and re-approve. This procedure ensures that changes and the current revision status of documents are identified, relevant versions of applicable documents are available at points of use, documents remain legible and readily identifiable, documents of external origin are identified and their distribution is controlled to prevent unintended use of obsolete documents, and documents are stored to prevent deterioration or loss.

4.2.5 Control of records

Records are maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records are legible, readily identifiable and retrievable, and changes remain identifiable.

Confidential health information contained in records will be protected.

The controls needed for the identification, storage, protection, retrieval, retention time and disposition of records have been defined in section 4.2.5 (Control of Records) of operating procedure 4.2 (“Documentation Requirements”).

5 Management responsibility

5.1 Management commitment

Top management (president and/or a vice-president) provides evidence of its commitment to the quality management system by communicating the importance of meeting customer (as well as regulatory) requirements, establishing the quality policy, ensuring that quality objectives are established, conducting management reviews and ensuring the availability of resources.

5.2 Customer focus

The president and vice-presidents ensure that customer and applicable regulatory requirements are determined and met with the aim of enhancing customer satisfaction through operating procedure 7.2 ("Customer-related Process") and section 8.2.1 (Feedback) of operating procedure 8.2 ("Monitoring and Measurement").

5.3 Quality policy

Our goal is to be a leader in the contract manufacturing services industry. We will accomplish this by meeting or exceeding our customers' expectations with regards to service (delivery, quality, pricing and response time) using well-defined procedures, well trained team members and repeatable processes.

Ernest V. Flamont
President

5.4 Planning

5.4.1 Quality objectives

Top management ensures that quality objectives are established at relevant functions and levels within Odyssey and are measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management ensures that the planning of the quality management system is carried out in order to meet the requirements given in 4.1 of this manual, as well as the quality objective. Top management also ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The interrelation of all personnel has been established. This interrelation, responsibilities and authorities are defined and communicated in the organizational chart in section 3 of this manual and within the operating procedures.

5.5.2 Management representative

The quality manager has been appointed by Odyssey's corporate president to have the authority and responsibility to ensure that processes needed for the quality management system are established, implemented and maintained. This manager reports to top management on the performance of the quality management system and any need for improvement and ensures the promotion of awareness of applicable regulatory and customer requirements through a database of complaints accessible throughout the organization.

5.5.3 Internal communication

Top management, through monthly (excluding January) employee meetings, ensures that appropriate communication takes place regarding the effectiveness of the quality management system.

Operating procedures 5.6 (“Management Review”) and 7.1 (“Planning of Product Realization”) demonstrate additional communication processes.

5.6 Management review

5.6.1 General

Top management and quality manager review Odyssey's quality management system, semiannually, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews are maintained.

5.6.2 Review input

Management review includes information on audit results, feedback and complaints, monitoring and measurement of product, preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, recommendations for improvement, and new regulatory requirements.

5.6.3 Review output

Management Review’s records include any decisions and actions related to improvements needed to maintain the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, and resource needs.

Reference section 5.6 to operating procedure 5.6 (“Management Review”).

6 Resource management

6.1 Provision of resources

The resources needed to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements are determined and provided.

6.2 Human resources

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

The organization determines the necessary competence for personnel performing work affecting product quality and provides training to satisfy these needs. It evaluates the effectiveness of the actions taken, ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, training, skills and experience.

Training needs are documented in the *Odyssey Electronics, Inc. Training Manual*.

Reference section 6.2 to operating procedure 6.2 (“Human Resources”).

6.3 Infrastructure

The infrastructure (the building, workspace, process equipment and supporting services) needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product have been determined, provided, documented and maintained.

Maintenance procedures are documented (to include frequency) and records are maintained.

Reference operating procedure 6.3 (“Infrastructure”) which includes all infrastructure requirements.

6.4 Work environment and contamination control

6.4.1 Work environment

The work environment determined to achieve conformity to product requirements is managed.

Operating procedure 6.4 (“Work Environment”) documents environmental (health, cleanliness, clothing or environmental conditions) requirements when affecting medical device safety or performance. These requirements include temporary departmental personnel per operating procedure 6.2 (“Human Resources”).

6.4.2 Contamination control

Where necessary, arrangements are established to control contamination.

Odyssey Electronic, Inc. does not use or build sterile medical devices, therefore, the sterilization sections of this standard do not apply.

7 Product realization

7.1 Planning of product realization

The processes needed for product realization are planned and developed. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see 4.1)

In planning product realization, the organization determines quality objectives; requirements for the product; and the need to establish processes, documents and resources specific to the product. During this planning, the required verification, validation, monitoring, inspection, test, storage, measuring, handling and traceablility activities specific to the product and the criteria for product acceptance are determined. Records provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).

This planning and the established requirements for risk management throughout product realization are defined in operating procedure 7.1 (“Planning of Product Realization”).

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Requirements specified by the customer, including the requirements for delivery and post-delivery activities; requirements not stated by the customer but necessary for specified or intended use, where known; applicable regulatory requirements related to the product; user training needed to ensure specified performance and medical device safety; and any additional requirements are determined.

7.2.2 Review of requirements related to the product

During the contract review process per operating procedure 7.2 (“Customer-related Processes”), requirements related to the product are reviewed and conducted prior to commitment to supply a product to the customer.

During this process, product requirements are defined and documented. Contract or order requirements differing from those previously expressed are resolved, the ability to meet the defined requirements and meet regulatory requirements are ensured prior to commitment. Any additional training required is identified.

Records of the results of the review and actions arising from the review are maintained (see 4.2.5).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance.

Where product requirements are changed, relevant documents are amended, and relevant personnel are made aware of the changed requirements.

7.2.3 Customer communication

Arrangements for communicating with customers in relation to product information, advisory notices, inquiries, contracts or order handling, including amendments, and customer feedback, including customer complaints are implemented.

Reference operating procedure 7.2 (“Customer Related Process”), section 8.2.1 (Feedback) of operating procedure 8.2 (“Monitoring and Measuring”), and operating procedure 8.5 (“Improvement”).

7.3 Design and development

Odyssey Electronic, Inc. does not design our manufactured products, therefore, the design sections of this standard do not apply.

7.4 Purchasing

7.4.1 Purchasing process

Purchased product conforms to specified purchase requirements. This procedure is documented in operating procedure 7.4 (“Purchasing”). The type and extent of control applied depends upon the effect of the purchased product on subsequent product realization or the final product.

Suppliers are evaluated and selected based on their ability to supply product, their performance and the effect of their product on quality. This selection and evaluation is proportionate to risk with the medical device. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.5), and the supplier is addressed of the actions.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased including product specifications, requirements for approval of product, procedures, processes and equipment; requirements for qualification of personnel; and requirements of the quality management system.

The adequacy of specified purchase requirements is ensured prior to communication to the supplier.

All changes in purchased product are communicated by the supplier and to the customer for approval prior to implementing any changes.

7.4.2 Purchasing information (continued)

Where traceability is required, procedures are created and records are stored per 7.5.9.

7.4.3 Verification of purchased product

Inspection and other activities necessary for ensuring that purchased product meets specified purchase requirements are implemented based upon supplier evaluation and proportionate to the risks. Records are maintained.

Where verification at the supplier's premises is performed, the intended verification arrangements and method of product release are stated in the purchasing information.

Reference section 7.4 to operating procedure 7.4 (“Purchasing”).

7.5 Production provision

Note: Odyssey Electronics, Inc. does not service our manufactured products, therefore, the “service” criteria in section 7.5 do not apply.

7.5.1 Control of production provision

Production provision is planned, carried out, monitored and controlled. These controls include, where applicable, all documentation for production; infrastructure; monitoring and measuring of process parameters and product characteristics; the availability and use of monitoring and measuring devices; and the implementation of release, delivery, post-delivery activities, and defined operations for labeling and packaging.

Reference section 7.5.1 to operating procedure 7.5 (“Production Provision”).

7.5.2 Cleanliness of product

Odyssey Electronics, Inc. does not produce any medical devices requiring sterilization or installation. If sterilization becomes required, documented procedures for 7.5.2 will be created.

7.5.3 Installation activities

Odyssey Electronics, Inc. does not produce any medical devices requiring sterilization or installation. If installation becomes required, documented procedures for 7.5.3 will be created.

7.5.4 Servicing activities

Odyssey Electronics, Inc. does not service our manufactured products, therefore, the “service” criteria in section 7.5.4 do not apply.

7.5.5 Particular requirements for sterile medical devices

When sterilization becomes required, records of process parameters will be maintained and traceable to each production batch.

7.5.6 Validation of processes for production provision

Any processes for production provision are validated where subsequent monitoring or measurement cannot verify the resulting output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results consistently.

7.5.6 Validation of processes for production provision (continued)

This validation is defined in section 7.5.6 in operating procedure 7.5 (“Production Provision”).

The application of computer software for production that affects the ability of the product to conform shall be validated, and records are maintained.

7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

Odyssey Electronics, Inc. does not produce any medical devices requiring sterilization. If sterilization becomes required, procedures for 7.5.7 shall be created, and records shall be maintained.

7.5.8 Identification

Product is identified by suitable means throughout product realization.

The product status, with respect to monitoring and measurement requirements, is identified. This identification is maintained throughout production and storage to ensure only product passing inspection and test is dispatched or used.

Reference section 7.5.8 to operating procedure 7.5.8 (“Identification”).

7.5.9 Traceability

7.5.9.1 General

The unique identification of the product is controlled and recorded where traceability is a requirement.

7.5.9.2 Particular requirements for implantable medical devices

Odyssey Electronics, Inc. does not manufacture implantable medical devices. When required to do so, a process for defining records for traceability will be created.

Reference section 7.5.9 to operating procedure 7.5.9 (“Traceability”).

7.5.10 Customer property

While customer property is under Odyssey's control or being used by Odyssey, it is identified, verified, protected and safeguarded. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.5).

Reference section 7.5.10 to operating procedure 7.5.10 (“Customer Property”).

7.5.11 Preservation of product

The conformity of product during processing, storage, handling and delivery is preserved through suitable packaging, containers and other document requirements for any special conditions. Such special conditions shall be recorded.

Reference section 7.5.11 to operating procedure 7.5.11 (“Preservation of Product”).

7.6 Control of monitoring and measuring equipment

Odyssey determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. (See 7.2.1.) Operating procedure 7.6 (“Equipment Calibration Process”) defines this process.

Processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements are established.
Where necessary to ensure valid results, measuring equipment is calibrated or verified at specified intervals, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded.

Measuring equipment is adjusted or re-adjusted as necessary, identified to enable the calibration status to be determined, safeguarded from adjustments that would invalidate the measurement result, and protected from damage and deterioration during handling, maintenance and storage. The validity of the previous measuring results when the equipment is found not to conform to requirements is assessed and recorded. Appropriate action on the equipment and any product affected is taken. Records of the results of calibration and verification are maintained (see 4.2.5).

When used in the monitoring and measurement of specified requirements, the application of computer software used for monitoring and measurement is validated proportionately to the risks, prior to initial use and reconfirmed after changes.

8 Measurement, analysis and improvement

8.1 General

To ensure conformity of the quality management system and to continually improve and maintain the effectiveness, the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product are planned and implemented. This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the performance of the quality management system, information relating to whether Odyssey has fulfilled customer requirements is monitored. The methods for obtaining this information and using it in our product realization and improvement processes are described in section 8.2.1 (Feedback) of operating procedure 8.2 (“Monitoring and Measurement”).

If post-production experience is required by national or regional regulations, Odyssey will use this experience in our feedback system.

8.2.2 Complaint handling

Customer complaints are recorded and maintained (see 4.2.5), pertinent suppliers shall be informed, and complaint will be investigated unless written justification per section 8.2.2 (Complaint Handling) of operation procedure 8.2 (“Monitoring and Measurement”), and corrective actions may be generated per operating procedure 8.5 (“Improvement”).

8.2.3 Reporting to regulatory authorities

Odyssey provides notification to the appropriate regulatory authorities if regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices per section 8.2.3 (Reporting to Regulatory Authorities) of operating procedure 8.2 (“Monitoring and Measurement”).

8.2.4 Internal audit

Internal audits are conducted at planned intervals to determine whether the quality management system conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by this organization and regulatory requirements. Internal Audits determine whether the Quality Management System is effectively implemented and maintained.

The planned audit program takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

Audit schedule and results are recorded (see 4.2.5).

The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Reference section 8.2.4 (Internal Audit) of operating procedure 8.2 (“Monitoring and Measurement”).

8.2.5 Monitoring and measurement of processes

Suitable methods are applied for monitoring and, where applicable, measuring of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrections and corrective action is taken, as appropriate.

8.2.6 Monitoring and measurement of product

To verify that product requirements have been met, characteristics of the product are monitored and measured. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements at product realization and operating procedure 7.5 (“Production Provision”).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product and identifies test equipment used for measurement, where appropriate (see 4.2.5).

Product release does not proceed until all the planned arrangements have been satisfactorily completed.

Odyssey Electronics does not manufacture implantable medical devices. When required to do so, personnel performing any inspection or testing will be identified and recorded.

Reference section 8.2.6 to operating procedure 8.2.6 (“Monitoring and Measurement of Product”).

8.3 Control of nonconforming product

Product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Operating procedure 8.3 (“Control of Nonconforming Product”) defines the authority and responsibilities and how nonconforming material is identified, segregated, evaluated (including the need for an investigation or third-party notification) and dispositioned.

8.3 Control of nonconforming product (continued)

Nonconforming product is either eliminated from possible use or used under concession with justification and approval by the quality manager, president or customer provided regulatory requirements are met.

When nonconforming product is detected after delivery or use has started, action is taken appropriate to the effects, or potential effects, of the nonconformity.

At any time, advisory notices in accordance with applicable regulatory requirements can be put into effect.

When nonconforming product is reworked it shall be re-verified to demonstrate conformity to the same acceptance criteria and regulatory requirements as the original product.

Records of the nature of nonconformities and any subsequent actions taken, including concessions, are maintained. (See 4.2.5.)

8.4 Analysis of data

Odyssey determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system.

The analysis of data provides information relating to feedback, conformity to product requirements, characteristics and trends of processes and products including opportunities for improvement, suppliers, and audits.

Where analysis of data proves the quality management system is not adequate or effective, corrective or preventive action shall follow per operating procedure 8.5.

Records of analysis results are maintained.

Reference section 8.4 to operating procedure 8.4 (“Analysis of Data”).

8.5 Improvement

8.5.1 General

Through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review the continued suitability, adequacy and effectiveness of the quality management system are ensured and maintained.

8.5.2 Corrective action

Prompt action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure defines requirements for reviewing nonconformities (including complaints); determining the causes of nonconformities; evaluating the need for action to ensure that nonconformities do not recur; planning, documenting and implementing action needed (including necessary documentation updates); records of the results of investigation and action taken; verifying that the action does not negatively affect the ability to meet regulatory requirements, safety or performance of the medical device; and reviewing effectiveness of corrective action taken.

8.5.3 Preventive action

Action is determined to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

8.5.3 Preventive action (continued)

A documented procedure defines requirements for determining potential nonconformities and their causes; evaluating the need for action to prevent occurrence of nonconformities; planning, documenting and implementing action needed; records of results of investigations and action taken; verifying that the action does not negatively affect the ability to meet regulatory requirements, safety or performance of the medical device; and reviewing effectiveness of preventive action taken.

Reference section 8.5 to operating procedure 8.5 (“Improvement”).