DEXTER MAGNETIC TECHNOLOGIES

Quality Policy

Revision B

Description				
Rev	Description	By	Approval	Date
A	Made stand-alone document from Quality Manual	CRL	CRL	11/16/2018
B	Added year/version of ISO and AS standards	GB	CRL	12/11/2018

Quality Policy

DEXTER MAGNETIC TECHNOLOGIES Inc. is a customer focused, magnetics industry leader, providing exceptional solutions through the effective use of a quality management system compliant with AS9100D:ISO9001:2015 and ISO13485:2016.

Dexter will:

- Meet all business and regulatory requirements
- Delight the customer
- Establish and review quality objectives
- Continually improve systems, processes, products and service.

[Signature on file] [Signature on file]

Clifford Long – Director of Quality Joe Stupfel – President

QUALITY MANUAL

1050 Morse Avenue
Elk Grove Village, Illinois 60007
847 956 1140 PHONE
847 956 8205 FAX
info@dextermag.com

Rev.	Description	Authorized	Issue Date
A	Initial Release	BD & KB	12/15/2016
B	Added interaction map and ISO 13485	BD & KB	10/04/2017
C	Updated with new management	CRL & JS	10/26/2018
D	Made Quality Policy stand-alone document. Minor corrections based on internal audit OFIs	CRL	11/16/2018
E	Update QMS interactions chart Other minor adjustments	CRL	03/13/2019

TABLE OF CONTENTS

Quality Policy

See DMT-QM Quality Policy

1.0 SCOPE

This manual defines the Dexter Magnetic Technologies (abbreviated DMT) Quality Management System (QMS), which meets or exceeds the requirements of the latest versions of AS9100D, ISO9001:2015 and ISO13485:2016.

Dexter Magnetic Technologies performs the design and manufacture of magnets and magnetic assemblies along with the distribution of specialized electronic products.

2.0 REVISIONS

A review of the documentation associated with the Quality Assurance System will be conducted, as a minimum, on an annual basis. All corrections, deletions and additions will be recorded on the Revision Record. The current revision of applicable documents at the date of contract will be in effect, unless a written change in contract is otherwise agreed upon.

2.1 DISTRIBUTION POLICY & DISTRIBUTION LIST

2.1.1 MASTER QUALITY ASSURANCE POLICY MANUAL:

The Quality Manager maintains a master copy of the signed Quality Policy. The electronic copy resides in Dexter's document control system and is the official released version. Once the document is printed or electronically transferred (such as by email), it becomes uncontrolled.

2.1.2 UNCONTROLLED COPIES

Uncontrolled copies of the Quality Manual are available to customers for reference only. These copies will not be automatically updated. It will be the holder's responsibility to verify that the copy in their possession is the current revision.

3.0 INTRODUCTION AND COMPANY PROFILE

Understanding Dexter Magnetic Technologies

Dexter Magnetic Technologies, Inc. is the best in the magnetics industry at transforming customer concepts and challenges into manufactured assemblies and highly engineered magnets. We achieve this by combining the industry's strongest engineering team with fast response times and deep customer relationships to deliver excellence in every aspect of the customer experience. The company was founded in 1951 under the name of Permag.

Dexter provides a broad range of materials, products and services, including; custom design and fabrication, assembly, magnetizing and testing with a focus on niche OEM and OEM like markets in developed countries where magnetic product / assembly performance and an understanding of regulatory requirements are required. Dexter maintains strong ties to interested parties, with an emphasis on our customers and supply base.

Dexter is registered with the DDTC to allow for production of ITAR products. Proof that one is a US person is required upon entry into the facility. If evidence is not provided, your access will be limited.

4.0 QUALITY MANAGEMENT SYSTEM

Dexter Magnetic Technologies has established, documented and implemented a Quality Management System in accordance with the requirements of AS9100:ISO9001 and ISO13485. This quality manual, with the quality policy, is the level A document.

Quality objectives, KPIs, are established and monitored on a regular basis as a measure of the adequacy of the DMT QMS.

The DMT Quality management system addresses customer and applicable statutory and regulatory requirements, whenever necessary. This quality system is maintained and continually improved.

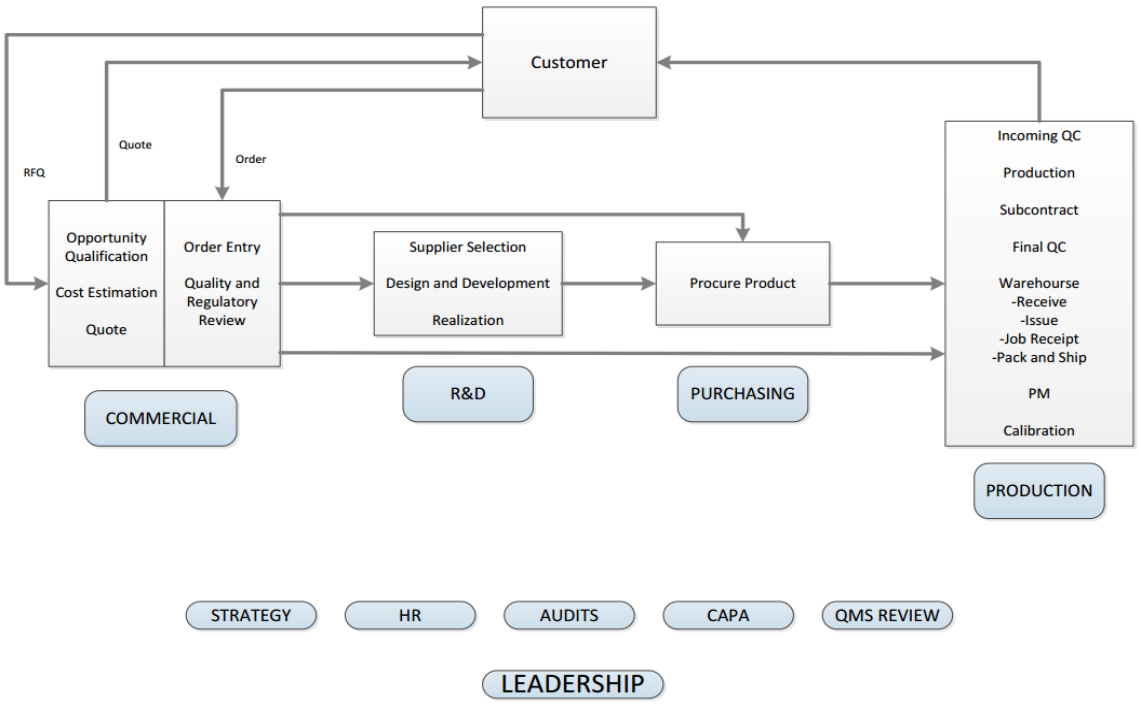
Documented business procedures required by the Standards and Dexter Magnetic Technologies (level B documents) have been established and are supported with work instructions, quality records and other level C documents. Contained in the appendix of each business procedure are the interactions (inputs and outputs) along with the measures used to determine the success of the process. Other production documents such as operation prints / assembly instructions have been created to ensure the effective planning, operation and control of our processes

Risk is analyzed for each business process, as applicable, through the use of a process FMEA.

The following sections of ISO 13485 are not applicable to the Dexter QMS because Dexter does not sterilize product: Section 6.4.2 paragraph 2, Section 7.5.5, Section 7.5.7, and Section 7.5.4 since Dexter does not service medical devices.

The process interactions are shown below and each business procedure includes inputs and outputs.

QMS Interactions Chart



The QMS interactions start and finish with the customer. The typical process is that the customer sends Dexter an RFQ, which goes through a cost estimation and quoting process, once the opportunity has been qualified. The quote is sent to the customer, who in turn places a PO. If the part is new, the order is routed through R&D for realization, if it is a repeat order it is routed directly to purchasing. The purchased parts are received by Dexter and routed through incoming inspection, if required, and then through the manufacturing process. Conforming parts are shipped to the customer. There are many QMS processes that do not directly affect product, but are used to ensure customer satisfaction and regulation compliance. This is all governed by the leadership team at Dexter.

4.1 Documentation/Record Requirements

4.1.1 Control of Documents

Dexter has created documents that govern the creation and control of documents.

A paper document is officially issued for use when it is approved by an authorized function, such as a customer or DMT drawing accompanying a job traveler. An electronic document is formally released and issued when the document author publishes it to Connexus, via EPDM.

Documents are distributed to personnel and locations where they are used. Electronic documents are available via Connexus and are accessible via relevant terminals and computers.

Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are automatically removed from Connexus when made obsolete from within EPDM.

Document changes are reviewed and authorized by the same function that issued the original document. Only the latest release and revision of a document is available from within Connexus.

Some documents of external origin, such as customer quality, statutory and regulatory requirements, are retained in the appropriate location. Unless otherwise specified, the current revision (the latest revision) of such documents shall be used.

Dexter Magnetic Technologies coordinates document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

References: DBP-100 'Quality System Documentation'
DBP-101 'Control of Documents'
DBP-103 'Control of Engineering Documents'
DBP-105 'Technology Control Plan'

4.1.2 Control of Quality Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Records remain legible, readily identifiable and retrievable. Documented procedure DBP-102 'Control of Quality Records' has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated and identify the product, person, or event to which they pertain. Records are indexed and grouped to facilitate their retrieval.

Retention periods for quality records are determined on the basis of procedure or on special customer requirements, regulatory and contractual requirements.

These requirements do not supersede any customer requirements. All specified retention periods are considered "minimums". Dexter Magnetic Technologies may dispose of records, after the designated retention times have expired.

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

References: DBP-102 'Control of Quality Records'

4.1.3 Device files

Device files may be created for parts or assemblies using form DF-001, Device File. The file will be created on an as-needed basis to help identify required information and storage locations. Storage location for the information in the device file is stored electronically in various locations within the Dexter network system. Since Dexter makes many products that are build-to-print, the description and the use/purpose of the end device is often not revealed to Dexter.

References: DF-001 'Device File'

5.0 LEADERSHIP/MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Management provides evidence of its leadership and commitment to the development and implementation of the QMS and to continually improve its effectiveness and meet the requirements of the latest version of the governing standards. A formal review is held every six months per DBP-104 Management Review.

5.2 Customer Focus

Management ensures that requirements (customer, statutory and regulatory) are determined and are met with the aim of enhancing customer satisfaction.

5.3 Quality Policy

Dexter Magnetic Technologies management has issued a quality policy.

The DMT Quality Policy is noted on page 5 of this Quality Manual (with a reference to the stand-alone document) and is posted throughout the facility.

5.4 Planning:

Planning shall occur when changes and potential changes occur that could affect the QMS.
Risk is evaluated at the quote stage for opportunities through Opportunity Qualification. Risk for processes and product is performed using FMEA, when appropriate.

5.4.1 Quality Objectives:

The DMT management has ensured that quality objectives are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the DMT quality policy. The Company's quality objectives are reviewed at a minimum as part of the Management Review.

Quality objectives have been developed for each main business process as appropriate and are used to measure process effectiveness and to drive continual improvement of these main processes.

5.5 Responsibility, Authority and Communication:

5.5.1 Responsibility and Authority

The Dexter Magnetic Technologies management team has ensured that the responsibilities and authorities are defined in the organization chart, quality manual, procedures and job descriptions and are communicated within the organization.

Departments, groups and functions within the company, and their relations, are defined in the organization charts that are available within the quality management system. All departments and functions in the company are responsible for implementing, maintaining, and improving the QMS.

QMS Management Representative

Dexter Magnetic Technologies has appointed the QMS Management Representative as the Management Representative, who, irrespective of other responsibilities, has the responsibility and authority that includes:

- Is a member of Management and provides a liaison with DMT Corporate Headquarters
- Facilitates the content of the Quality Policy with the Executive Management Team
- Provides resources necessary to maintain and improve the QMS
- Conducts management reviews of the QMS
- Ensures functional compliance with the QMS
- Identifies opportunities for improvement of the QMS
- Works with the Executive Management Team to ensure that processes needed for the QMS are established, implemented and maintained
- Reports to Executive Management on the performance of the QMS and any need for improvement
- ensuring the promotion of awareness of customer requirements throughout the organization
- the organizational freedom and unrestricted access to management to resolve quality management issues

  The Director of Quality has been designated as the QMS Management Representative with the Vice President of Operations being designated as the Alternate (Deputy) Management Representative in the absence of QMS Management Representative.

Quality

- Ensures audits of implementation and effectiveness of the QMS
- Ensures quality inspections and monitors inspection data
- Assists in documenting quality planning
- Maintains the calibration system
- Ensures receiving, in-process (as applicable) and final inspection
- Monitors nonconforming material reporting system and analysis of data
- Monitors return material and analysis of data
- Monitors the Corrective and Preventative Action system and records
- Reviews and manages the Oasis Database

Operations

- Plans production, facilities, equipment, and processes
- Ensures production schedules, controls and verifications
- Ensures the development of process and assembly operator instructions
- Carries out print reviews
- Recommends non-inventory suppliers and subcontractors for qualification
- Ensures first article and in-process inspections
- Ensures in-process product identification is maintained

- Ensures maintenance of production equipment
- Ensures personnel qualification requirements and ensures training
- Ensures the receiving and finished product stockroom
- Ensures product packaging and shipment to customers

Technology
- Develops product design
- Documents design input specifications
- Designs products and product improvements
- Conducts design reviews
- Verifies and validates designs
- Documents design outputs
- Assists in product realization and verification planning

Purchasing
- Prepares and approves purchasing documents
- Monitors and evaluates supplier and subcontractor performance
- Verifies product identification for purchased products
- Recommends inventory suppliers for qualification

Sales & Marketing
- Conducts market research to anticipate customer expectations
- Establishes specifications for new products
- Advertises and promotes company's products
- Monitors the quality performance of competitors
- Carries out contract and order reviews
- Provides customer liaison and service
- Provides product information
- Handles customer feedback and complaints
- Provides analysis and monitors customer feedback and satisfaction

Human Resources
- Formulates policies and prepares forms related to Human Resources to ensure that employees are made aware of company practices and processes
- Defines qualification requirements of functional personnel
- Oversees training of functional personnel
- Determines the requirements for internal and external training that will accelerate the worker’s technical and personal development and actualizes these training programs
- Counsels company employees
- Prepares payrolls and manages insurance procedures
- Investigates alleged violations of company’s policies and practices
- Determines the appropriate level of disciplinary action
- Handles initial selection and request of employee benefits

5.5.2 Internal Communication

The Dexter Magnetic Technologies management has ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

5.6 Management Review

Dexter Magnetic Technologies management reviews the organizations QMS, on a semi-annual basis, to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. Records of these reviews are maintained. Management review will be conducted to meet the requirements of the latest version of AS9100:ISO9001 and ISO13485.

References: DBP-104 'QMS Review'

6.0 SUPPORT/RESOURCE MANAGEMENT

6.1 Provision of Resources

Dexter Magnetic Technologies has determined and provides the resources needed to establish, implement, maintain and improve the QMS by understanding the internal resource capabilities and constraints along with what needs to be obtained from external providers.

Dexter provides the people, infrastructure and environment necessary to satisfy the requirements of the QMS.

References: DBP-200 'Infrastructure and Work Environment'
DBP-201 'Resource Management'
DBP-202 'Equipment Installation and Maintenance'

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization:

Dexter Magnetic Technologies plans and develops the processes needed for product realization. Planning of product realization is consistent with the processes of the QMS and is undertaken to ensure that quality and schedule are not compromised.

In planning product realization, Dexter Magnetic Technologies takes into account as appropriate the requirements for the product and processes.

7.1.1 Project Management

DMT plans and manages product realization in a structured and controlled manner, i.e. to meet requirements at acceptable risk, within the constraints of resources and schedules.

7.1.2 Risk Management

DMT has established, implemented and maintained a risk management process. Risk for processes and product is performed using FMEA, when appropriate.

7.1.3 Configuration Management

Dexter Magnetic Technologies has established and maintains a documented configuration process appropriate to the products it manufactures.

7.1.4 Control of Work Transfers

Dexter Magnetic Technologies has established and maintains a process to plan and control the temporary transfer of work (outside operations) from Dexter to the subcontractor and verifies the conformity of the work to requirements upon receipt.

7.1.5 Product Safety

Dexter Magnetic Technologies takes precautions to ensure that safety is maintained throughout the product life cycle by evaluating the manufacturing process and shipment packaging for appropriate safety considerations.

7.1.6 Prevention of Counterfeit Parts

Dexter Magnetic Technologies takes precautions appropriate to the organization and the product, for the prevention of counterfeit parts by purchasing from original manufacturers, authorized distributors, or other Dexter approved sources. Dexter also maintains requirements for assuring traceability of parts and components. If counterfeit material is found, it will not be returned back to the supply chain.

7.2 Customer-Related Processes

7.2.1 Determination and Review of Requirements Related to the Product

Dexter Magnetic Technologies determines the requirements specified by the customer and any additional requirements identified by Dexter Magnetic Technologies.

DMT reviews the requirements related to the product. This review is conducted prior to Dexter Magnetic Technologies' commitment to produce a product for the customer. Dexter Magnetic Technologies maintains records of the results of the review and actions arising from the review.

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

When product requirements change, Job travelers and other relevant documents are amended and relevant personnel are made aware of the changed requirements.

7.2.2 Customer Communication

DMT has determined and implemented effective arrangements for communicating with customers relating to product information, enquiries, order handling, including amendments, and customer feedback, including customer complaints.

References: DBP-400 'Opportunity Qualification'
DBP-402 'Sales Estimation Quote and Follow up'
DBP-404 'Order Entry Review and Acknowledgement'
DBP-406 'Customer Feedback'
DBP-800 'Quality and Regulatory Review'

7.3 Design and Development

7.3.1 Design and Development Planning

The design process has been planned and implemented with respect to the organization, task sequence, mandatory steps, significant stages and method of configuration control.

When necessary due to complexity, Dexter Magnetic Technologies gives consideration to the following activities: structuring the design effort into distinct elements, and for each element define the tasks, the necessary resources, responsibilities, design content, input and output data and planning constraints. The input data specific to each element is reviewed to ensure consistency with requirements.

The different tasks are based on the safety and functional objectives of the product, taking into consideration customer, statutory and regulatory requirements. Planning also considers the ability to produce, inspect and test the product. Design and development plans are continually updated, as appropriate, as the process progresses.

7.3.2 Design and Development Inputs

The project team identifies the primary design input requirements and the required records.

In the case of products developed for a specific customer, the results of the contract review activities shall be incorporated as part of the design input.

The project team resolves incomplete, ambiguous, conflicting, or impractical requirements. Upper levels of management are consulted if the project team cannot resolve design requirement issues.

7.3.3 Design and Development Outputs

Design output is documented in the form of numbered drawings with appropriate revision control, test results, calculations, and measurements as applicable. The output must meet the input requirements and be in a form that enables verification. All data records are stored based on a smart numbering system.

Test data is accumulated to check the performance of the product against the input requirements.

The outputs will be approved prior to release. Other nonperformance related characteristics are also checked as well as the appropriate information for purchasing, production, and service.

All applicable standards, including appropriate electrical, mechanical and magnetic, will be adhered to where applicable. Characteristics essential for safe usage and conformance to applicable safety and environmental regulations are also addressed. The key characteristics of the product, when applicable in accordance with a specific design or contractual requirement are also identified.

For Dexter designs, all pertinent data required allowing the product to be identified, manufactured, inspected, used and maintained safely and properly shall be defined by Dexter Magnetic Technologies.

7.3.4 Design and Development Review

Formally planned and documented design reviews are to be undertaken at appropriate stages of each development program. The project team, including engineering personnel, as well as other concerned specialists, will participate in the design review process, as required. Subject matter experts are included when appropriate.

Records are maintained of the design reviews and any necessary actions.

7.3.5 Design and Development Verification

Design verification will be undertaken at appropriate stages of the development effort to ensure that the design outputs meet the design input requirements. Design reviews are included as part of design verification. Records of the verification and any necessary actions are maintained.

7.3.6 Design and Development Validation

Design validation is undertaken wherever practical before production release. This is done to ensure that the product ultimately meets the planned arrangements and the specified requirements.

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented.

At the completion of each development effort, DMT ensures that reports, calculations, test results, etc. demonstrates that the product definition meets the specification requirements for all identified operational conditions.

7.3.7 Control of Design and Development Changes

All design changes and modifications shall be identified, documented (records created), reviewed, verified, validated, and approved by authorized personnel before their implementation. When required by contract or purchase order, approval for design changes also shall be obtained from the customer and/or regulatory agency.

All design changes will be evaluated as to their effect on constituent parts or product already delivered.

Design and development changes are controlled in accordance with the DMT configuration management process per DBP-103, Control of Engineering Documents.

References: DBP-502 ‘Design and Development’

7.4 Purchasing

7.4.1 Purchasing Process

Dexter Magnetic Technologies has evaluated and selected suppliers based on their ability to provide service in accordance with Dexter Magnetic Technologies requirements. Records are maintained to document the evaluation and selection process.

Dexter Magnetic Technologies is responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

Supplier compliance to part print(s) implies that the risk for that part is acceptable for the end use application of the part.

7.4.2 Purchasing Information

Dexter Magnetic Technologies purchasing information describes the service to be purchased and any requirements by the customer, regulatory and Dexter.

Dexter Magnetic Technologies ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

Dexter Magnetic Technologies has established and implemented the activities necessary for ensuring that purchased product meet specified purchase requirements.

Purchased product that is used or processed prior to verification as conforming, is identified sufficiently to permit recall, if necessary.

Where Dexter Magnetic Technologies utilizes test reports to verify purchased product or service, the data in those reports periodically shall be verified as acceptable per applicable specifications when those products/services are determined to be critical to the end products, i.e. when the risk of nonconformance is considered to be high.

Neither Dexter Magnetic Technologies nor its customers presently perform verification at the supplier's premises. However, if this is a requirement in the future, verification arrangements and method of product release will be specified in the DMT purchasing information.

Where specified in contracts, the customer or customer's representative will be afforded the right to verify at Dexter Magnetic Technologies premises and the suppliers premises that subcontracted product conforms to specified requirements.

Dexter Magnetic Technologies understands that verification by the customer at any point in the supply chain cannot be used as evidence of effective control of quality or to verify conformity of product. This does not absolve Dexter Magnetic Technologies of the responsibility to provide acceptable product.

References: DBP-700 'Supplier Approval and Evaluation'
DBP-701 'Purchasing Process'
DBP-801 "Incoming Inspection"

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Dexter Magnetic Technologies considers the establishment of process controls and development of control plans where key characteristics have been identified and are required by the customer. In-process verification of conformance is performed when conformance cannot be performed at a later stage of production. Engineering considers the use of tooling so that variable measurements can be taken, particularly for key characteristics and special processes.

Dexter Magnetic Technologies plans and carries out production and service provision under controlled conditions. Controlled conditions includes as applicable

References: DBP-604 'Control of Production and Service Provision'
DBP-613 'Process Documentation'

7.5.1.1 Production Process Verifications

For the first production run of a new part or assembly, or when required by the customer, the Company conducts and documents formal first article inspection to verify that production processes, documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is also repeated when changes are made that invalidate the original results.

7.5.1.2 Control of Production Process Changes

Manufacturing Engineering and the Director of Operations have authority to change manufacturing processes. Dexter Magnetic Technologies identifies and obtains acceptance of changes that requires customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and software programs are documented. The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

Validated processes require an IQ, OQ and PQ. Any change to a validated process requires the approval of the Director of Quality approval prior to making the change.

Dexter Magnetic Technologies maintains records of process change effective dates.

References: DBP-604 'Production Control'

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control & monitor product realization processes are validated prior to use and are maintained appropriately.

Storage requirements, including periodic preservation/condition checks, have been determined for production equipment or tooling in storage.

7.5.1.4 Post Delivery Support

DMT accepts return material and is replacing it as required by customers. CAPAs are originated when appropriate and completed using a 7D process.

References: DBP-604 'Control of Production and Service Provision'

7.5.2 Validation of Processes for Production

DMT validates all processes for production where the resulting output cannot be verified by subsequent monitoring or measurement. This includes Dexter Magnetic Technologies processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation demonstrates the ability of DMT processes to achieve planned results. Dexter Magnetic Technologies has established arrangements for these processes.

DMT does not perform any special processes.

7.5.3 Identification and Traceability

Dexter Magnetic Technologies identifies the product by the job traveler throughout product realization. The Company maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Dexter Magnetic Technologies identifies the product status with respect to monitoring and measurement requirements on the Traveler. When traceability is a requirement for DMT; Dexter Magnetic Technologies records the unique identification of the product.

According to the level of traceability required by contract, regulatory authority, or other established requirement, Dexter Magnetic Technologies provides for identification to be

maintained throughout product lifecycle. All products are traced through production from the manufacturing batch, as well as the destination (delivery, scrap) of all products of the batch, for an assembly (including components) and the next higher assembly, for a given product. A sequential record of its production (e.g. assembly, outside operations, inspection) is maintained and can be retrieved.

7.5.4 Customer Property

The Company exercises care with customer property while it is under Dexter Magnetic Technologies control. DMT identifies, verifies, protects and safeguards customer property. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

7.5.5 Preservation of Product

Dexter Magnetic Technologies preserves the conformity of product during manufacturing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage, and protection.

Preservation of product also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for cleaning, prevention, detection and removal of foreign objects, special handling for sensitive products, marking and labeling including safety warnings, shelf life control and stock rotation and special handling for hazardous materials.

References: DBP-600 'Receiving Material'
DBP-606 'Foreign Object Debris Damage'
DBP-608 'Jobs Receipt to Stock'
DBP-609 'Pick Pack and Ship'

7.6 Control of Monitoring and Measuring Equipment

Dexter Magnetic Technologies 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.

DMT maintains a register of these monitoring and measurement devices, and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. The Company uses the GageTrak software to manage the recall and data collection of the devices in the calibration system.

DMT has established 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, including suitable environmental conditions.

Records of the calibration activity for all gages, measuring, and test equipment, including those owned by employees are maintained.

Dexter Magnetic Technologies assesses and records the validity of previous measuring results when the equipment is found not to conform to requirements. Dexter Magnetic Technologies takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

References: DBP-804 'Control of Measuring & Monitoring Equipment'

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Dexter Magnetic Technologies has planned and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the QMS, and to continually improve the effectiveness of the QMS.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use. According to the nature of the product and depending on the specified requirements, statistical techniques may be used.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, Dexter Magnetic Technologies monitors information relating to customer perception as to whether it has met customer requirements.

Dexter Magnetic Technologies Quality Policy relates directly to customer satisfaction. The Company continually monitors customers' perception of our quality achievements by maintaining open customer communication. In addition, DMT monitors product performance, customer corrective action requests, returned goods (RMA requests), warranty claims, and on-time delivery.

When data indicate areas of dissatisfaction, the Company takes appropriate action to correct the areas of deficit and subsequently assesses the effectiveness of these actions.

References: DBP-405 'Customer Satisfaction'

8.2.2 Internal Audit

Dexter Magnetic Technologies conducts internal audits at planned intervals to determine effectiveness and conformance to the QMS.

The DMT audit program is planned, taking 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. Company auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined. Internal audits are conducted according to an audit plan, review annually and updated as required. When internal/external nonconformities or customer complaints occur, the planned audit frequency may be increased.

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.

Internal audits also meet contract and/or regulatory requirements.

Records of the internal audits, including resulting corrective action and objective evidence of subsequent verification activities, are maintained.

References: DBP-805 'Internal Audit'

8.2.3 Monitoring and Measurement of Processes

DMT applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate.

8.2.4 Monitoring and Measurement of Product

Dexter Magnetic Technologies monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements. Measurement requirements for product acceptance are performed as appropriate.

When critical items, including key characteristics, have been identified, they are monitored and controlled.

When DMT uses sampling inspection as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles as appropriate for use. When required, the plan will be submitted for customer approval.

As a policy, product is not used (i.e. released for production) until it has been inspected or otherwise verified as conforming to specific requirements. In the special circumstance where the product is released prior to inspection, it is identified and recorded to permit recall or replacement if it subsequently found to be nonconforming.

Evidence of conformity with the acceptance criteria is maintained. When required to demonstrate product qualification Dexter Magnetic Technologies ensures that records provide evidence that the product meets defined requirements. Records indicate the person(s) authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

DMT makes a conscious effort to ensure that documents required by the customer to accompany the product are present at delivery and are protected against loss and deterioration.

References DBP-802 'Final Inspection'

8.3 Control of Nonconforming Product

Dexter Magnetic Technologies ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions has been established.

Dexter Magnetic Technologies deals with nonconforming product by taking action to eliminate the detected nonconformity. Disposition of the product is by authorizing use as is, repair, release or acceptance under concession by the relevant design authority.

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

In addition to any contract or regulatory authority reporting requirements, Dexter Magnetic Technologies system provides for timely reporting of delivered nonconforming product that may affect reliability or safety. If a Customer complaint for a medical device requires an advisory notice, follow the process defined in DBP-806 'Corrective and Preventive Action'.

DMT does not use disposition of use-as-is or repair, unless specifically authorized by the customer, if the product is manufactured to customer design or the nonconformity results in a departure from the contract requirements.

Product disposition for scrap is positively controlled while awaiting disposition. When the disposition is scrap at DMT, the product is either rendered physically unusable by being mechanically altered or by being placed in the scrap container. Scrap may be conspicuously and permanently marked until placed in the scrap container or positively controlled until physically rendered unusable.

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained are maintained.

References: DBP-611 'Control of Nonconforming Product'
DBP-618 'Returned Material Control'

8.4 Analysis of Data

Dexter Magnetic Technologies determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources such as; Customer Satisfaction, Contract Requirements, Internal Audit Results, Conformity to Product Requirements, Corrective/Preventive Actions, Supplier Performance and Trends. Statistical techniques may be used, but are not typically used for analysis of data.

8.5 *Improvement*

8.5.1 Continual Improvement

Dexter Magnetic Technologies continually improves the effectiveness of the QMS through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The Company continually improves quality and service that benefits its customers. Continual improvement also includes product characteristics. DMT monitors the implementation of improvement activities and evaluates the effectiveness of these activities. The Organization demonstrates knowledge of appropriate continuous improvement measures and uses those that are appropriate.

References: DBP-104 'QMS Review'

8.5.2 Corrective Action

Dexter Magnetic Technologies takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformity encountered.

References: DBP-806 ‘Corrective and Preventive Action’

8.5.3 Preventive Action

Dexter Magnetic Technologies determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

References: DBP-806 ‘Corrective and Preventive Action’