

Introduction

TNT EDM, Inc. has developed, implemented and maintains a Quality Management System to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements and to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements. The Quality Management System has been developed to meet the Requirements of **AS9100C/ISO 9001:2000**, **ISO-9001:2008**, **ISO – 13485:2003** and **(USNRC – 10 CFR Part 21)**

This Quality Manual is divided into five sections corresponding to the format of the Quality System requirements of **AS9100C/ISO 9001:2000**; and the specific additional requirements governing **ISO – 13485:2003**, and **(USNRC – 10 CFR Part 21)**, are addressed within the Clause pertaining thereto. The Quality Management System requirements specifically addressing the ISO-9001:2000 Requirements are identified via standard block font; the additional **AS9100C Aerospace additional requirements are identified via Bold Faced Font and “Highlighted in Yellow”**; **ISO-9001:2008 Requirements are identified via Bold Faced Italic Font and Highlighted in Blue**, and the additional Requirements for **ISO-13485 “Medical Devices and Instrumentation including Design and Orthopedic Implants, are identified via Bold Faced “Blue Color Font”**; and the Requirements for **USNRC -10 CFR Part 21 “Nuclear Safety Related (including ASME III) Material Cutting and Machining Processes – Per EPRI NP-5652 as conditionally endorsed by USNRC GL-89-02; Method 2”**, are identified via **Bold Faced Orange Color Font**. Each section starts with a general policy statement expressing the commitment to implement the basic principles of the Quality Management System that is the subject of the section. The general policy statement is followed by more specific procedural policies outlining how the general policy is carried out and referencing the applicable work instructions and forms or checklists utilized.

The purpose of this manual is to define and describe the Quality Management System, to define the authorities and responsibilities of the management personnel affected by the system and to provide general procedures for all activities comprising the Quality Management System.



Quality Assurance Manual

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Mission Statement

To be the premier manufacturer of quality molds, dies and punches which provide the best value to our customers.

Values

The following values are essential to achieving our mission:

At TNT EDM, our people are our most important resource. The contribution of each employee to the quality of our products and to achieving total customer satisfaction is the basis for our continuing growth and success. We will constantly strive to maintain an atmosphere where our employees can exercise personal initiative, fully utilize individual talents and feel a sense of pride and value.

Quality Policy

TNT EDM, Inc. will provide best in class products and services to meet or exceed our customers' cost, quality, reliability and delivery requirements and their future expectations. TNT EDM is dedicated to continuous improvement in all facets of its business to enhance our customers' and TNT EDM's continued long term profitable growth.

Section 4

Quality Management System

4.1 General

TNT EDM has established, documented and maintains a Quality Management System and continually improves its effectiveness, in accordance with the requirements of this International Standard. TNT shall also address customer and applicable statutory and regulatory quality management system requirements. In meeting with the above, TNT EDM shall:

- **Determine** the processes needed for the Quality Management System and their application throughout the organization – To meet this requirement, TNT EDM has developed and implemented Key Process Maps which are in the format of “Turtle Diagrams”; and are broken down into Customer Oriented Processes (COP’s), Support Oriented Processes (SOP’S), and Management Oriented Processes (MOP’s). There have been 17 Key Processes defined ([KP-0001](#) through [KP-0017](#)), which identifies TNT’s processes. Each Turtle Diagram identifies the Process Owner(s), Inputs, Outputs, Materials/Equipment, Competence/Skills/Training, Methods/Procedures/Techniques and Measurement/Assessment.
- Determine the sequence and interaction of these processes – **This requirement is met via the Process Map, which shows the linkage of TNT EDM’s Customer Oriented Processes (COP’s), Support Oriented Processes (SOP’S), and Management Oriented Processes (MOP’s); and also is linked to Procedure, Work Instruction and Forms used within the documented QMS.**
- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective. This is accomplished via a combination of Internal and External Quality Management System Audits, monthly BOS Management Review Meetings, and Customer Satisfaction metrics such as Awards and Customer Concerns/Complaints.
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes. This is accomplished via allocation of the necessary time resource with which to effectively monitor, measure, report on, and evaluate the effectiveness of our Key Processes.
- Monitor, measure **where applicable**, analyze these processes. This is accomplished via the monthly BOS Management Review Meetings during which trends in operational and Key Business Measurables are tracked, monitored, measured, reported on and evaluated for the effectiveness of our Quality Management System.

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- **Implement actions necessary to achieve planned results and continual improvement of these processes** – This is accomplished via the management review output process.

The methods by which the above requirements are met are detailed within the following sections throughout the body of this Quality Assurance Manual.

These processes shall be managed by TNT EDM in accordance with the requirements of **AS9100C/ISO 9001:2008**, International Standard.

Where TNT-EDM, Inc., chooses to outsource any process that affects product conformity to requirements, TNT-EDM, Inc., shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system

Note 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement and analysis and improvement.

Note 2: An “outsourced process” is a process that TNT-EDM, Inc., needs for its quality management system and which TNT-EDM, Inc., chooses to have performed by an external party.

Note 3: Ensuring control over outsourced processes does not absolve TNT-EDM, Inc., of the responsibility of conformity to all customers, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- a) The potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,**
- b) The degree to which the control for the process is shared,**
- c) The capability of achieving the necessary control through the application of clause 7.4.**

4.2 Documentation Requirements

4.2.1 General

TNT EDM’s Quality Management System documentation includes the following:

- Documented statements of a quality policy and quality objectives – TNT EDM’s Quality Policy has been developed, implemented and is maintained throughout the organization. Quality objectives are in the format of Key Business Measureables, which members of the Steering Committee serve as champions with the responsibility

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to track, monitor and report on at monthly Steering Committee meetings.

- This Quality Manual has been developed and implemented to meet the requirements of **AS9100C/ISO 9001:2008**, **ISO – 13485:2003**, and **(USNRC – 10 CFR Part 21)**.
- Documented procedures **and records**, required by **AS9100C/ISO 9001:2008**, **ISO – 13485:2003**, and **(USNRC – 10 CFR Part 21)** are addressed within the appropriate sub-sections of this quality manual; and include but are not limited to the following six processes: 4.2.3 (Control of Documents), 4.2.4 (Control of Quality Records), 8.2.2 (Internal Audits), 8.3 (Control of Nonconforming Product), 8.5.2 (Corrective Action), and 8.5.3 (Preventive Action).
- **Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.**— these may include documents such as Job Traveler (VISTA), Forms, Checklists, and/or other types of Inspection and Testing result records.
- Records required by **AS9100C/ISO 9001:2000**, **ISO-9001:2008**, **ISO – 13485:2003**, and **(USNRC – 10 CFR Part 21)** – are addressed within section 4.2.4 (Control of Quality Records), and are identified on the Quality Records Master List. ([TNT-F-0006](#))
- **Quality System Requirements imposed by the applicable Regulatory Authorities.**
- **Any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.**

Note: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

For each type or model of medical device, TNT EDM shall establish and maintain a file either containing or identifying documents defining product specifications and Quality Management System requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

The above described Quality Management System documentation is structured according to the following format:

- Level One (Policies) and Level Two (Procedures) are in the combined format of this Quality Manual.
- Level Three (Work Instructions) – are structured as follows:
TNT = TNT EDM, WI = Work Instruction, 0001 = first work instruction.

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(ex. [TNT-WI-0001](#) = first work instruction in the system,
[TNT-WI-0002](#) = second work instruction in the system.

- Level Four (Forms, Checklists) – are structured as follows:

TNT = TNT EDM, F= Form, 0001 = first form

(ex. TNT-F-0001 = first form/checklist in the system

TNT-F-0002 = second form/checklist in the system

Four digit sequential number = the number of the work instruction, or form/checklist as identified on the Master List of Controlled Documents (TNT-F-00020) which identifies the Work Instruction or Form Number, the revision level, and date of implementation of that revision.

4.2.2 Quality Manual

TNT EDM has developed, implemented and maintains a quality manual that includes:

- The scope of the Quality Management System, **which does not include** any exclusions, **is as follows**: For **AS9100C/ISO 9001:2000, ISO-9001:2008** – “**The Manufacture of Molds, Dies and Punches; Specializing in Electric Discharge Machining (EDM)**”. For **ISO-13485:2003 the Scope is: The design and manufacture of molds, dies, punches and medical devices including; Functional and Passive Implants (Orthopaedic Implants), Surgical Instruments and Disposables; specializing in Electric Discharge Machining (EDM) and 5 Axis Milling**. The Scope is expanded to include: “**Nuclear Safety Related (including ASME III) Material Cutting and Machining Processes – Per EPRI NP-5652 as conditionally endorsed by USNRC GL-89-02; Method 2**”.
- The documented procedures established for the Quality Management System, or reference to them. The six required documented procedures are: 4.2.3 (Control of Documents), 4.2.4 (Control of Quality Records), 8.2.2 (Internal Audits), 8.3 (Control of Nonconforming Product), 8.5.2 (Corrective Action), and 8.5.3 (Preventive Action).
- A description of the interaction between the processes of the Quality Management System – This is accomplished via the Documentation & Process Cross Reference Matrix for **AS9100C/ISO 9001:2000, ISO-9001:2008**, form which shows the linkage of each of the Clauses of **AS9100C/ISO 9001:2000, ISO-9001:2008**, Standard; with the TNT EDM Procedure, Work Instruction, Forms, the Key Process Map pertaining to the specific clause and the Process Owner(s).
- **This Quality Manual shall outline the structure of the documentation used in the Quality Management System – this is defined above.**

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4.2.3 Control of Documents

- Documents required by the Quality Management System shall be controlled. Quality records are a special type of document and shall be controlled according to the requirements given in section 4.2.4 (Control of Quality Records). Documents may be any form or type of medium, such as: Paper (“hard copy”), Magnetic, Electronic or Optical Computer Disc, Photograph, or Master Sample.
- TNT EDM has developed and implemented the following procedures and controls needed to:
- **To Review and Approve documents for adequacy prior to use** – Documents and data are reviewed and approved by authorized personnel prior to issue and use. Depending upon the nature of the document or data, the authorized personnel may include the Quality System Manager, Project Managers and/or President. The Quality System Manager has the authority to approve and implement procedures, work instructions, inspection instructions and forms/checklists necessary for the effective operation of the Quality Management System on an immediate basis. These documents are controlled by the **Quality System Manager**. The **Quality System Manager** has password protected full access as appropriate, to enable editing of the documents (when required). Whenever it is deemed necessary to revise these documents and/or to issue new documents in order to maintain ongoing effective operation of the Quality Management System; the Quality System Manager, who as a member of the Steering Committee, presents these new and/or revised documents to the Steering Committee during the regularly scheduled monthly meetings for their concurrence. Other documents such as Engineering Drawings, Math (CAD) Data, Material Specification, Engineering Standards - the Engineering Department personnel have the authority, under the direct responsibility of the Project/**General Manager**, to maintain control over these documents.
- Review and update as necessary and re-approve documents– Documents such as procedures, work instructions and form/checklists. The Steering Committee, at the regularly scheduled monthly meetings, has the responsibility and authority for controlling this process.
- Ensure that changes and the current revision status of documents are identified – Master List Document Control has been developed and implemented (TNT-F-00020). This form identifies the type of document, name of the document, revision number and effective date the revision level was implemented. There is a separate Master
- List for Forms/Checklists, Work Instructions, Customer Standards/Specifications and External Reference Manuals. These documents are electronically controlled, with the Quality Control Manager having the access for editing as necessary. The Engineering Department personnel have the responsibility and authority to maintain effective controls over the revision status of electronically controlled documents such as CAD files. In addition, for control of revisions to drawings, TNT EDM has developed and implemented

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the following work instructions:

- Verbal Drawing Change Process ([TNT-WI-0013](#))
- Drawing Revision Control Process ([TNT-WI-0014](#))
- Ensure that relevant versions of applicable documents are available at points of use- All electronically controlled documents are linked to the Network which ensures that only the current applicable version of the document needed can be accessed for point of use by the process performer. In addition, the appropriate personnel (process performer) have been trained on how to access the documents electronically, which may be necessary for the effective operation of the Quality Management System. This is accomplished by virtue of the fact that there is computer network access within each department of TNT EDM's organization. In some manufacturing areas where "hard copies" of work instruction binders may be centrally located, it is the responsibility and authority of the Quality Assurance Manager to maintain control by virtue of a distribution listing of where hard copies of documents are utilized.
- Ensure that all documents utilized within TNT EDM's organization, which are computer generated ensures clear legibility and readily identifiable. All other documents such as "hard copy" of drawings are inspected prior to use, to insure their legibility and identification status.
- Ensure that documents of external origin **determined by the organization to be necessary for the planning and operation of the Quality Management System** are identified and their distribution controlled – TNT EDM has developed a Master List of Controlled Documents for Customer Standards/Specifications and External Reference Manuals. The appropriate personnel who require these documents for their process performance are tracked via the distribution list for controlled documents.
- Prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose – all obsolete documents are stamped "Obsolete" in red ink and removed from the point of use; unless such a document is deemed necessary to be used for "Reference"; it is still clearly stamped with the red "Obsolete" stamp or placed in the Obsolete folder on the network.

TNT EDM's Network Administrator has the access to all electronic data within the organization, and maintains a log of the "Passwords" of all personnel authorized for access to the network. In addition, in order to preserve and protect "all" electronic data generated and used, a work instruction for File Backup Procedure ([TNT-WI-0001](#)) has been developed and implemented.

TNT- EDM coordinates document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements, when applicable.

TNT EDM shall ensure that changes made to documents are reviewed and approved by the original approving function or another designated function which has access to

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pertinent background information upon which to base its decisions.

TNT EDM shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by TNT EDM, but not less than the retention period of any resulting record (see 4.2.4) or as specified by relevant regulatory requirements. To accomplish this requirement, the following has been implemented: Since all documents maintained by TNT EDM are in electronic format, obsolete controlled documents are downloaded into an “Archived Electronic Documents” folder and are maintained for a period of three years from the date of the revisions; or may otherwise be specified by the Customer and/or Government or Regulatory Requirements, which may supersede the established retention period, as applicable.

4.2.4 Control of Quality Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System **shall be controlled**. TNT EDM has developed, implemented and maintains the following procedure which defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

All quality records are maintained in such a manner that they are legible, stored and protected so that they are identifiable and readily retrievable (by authorized personnel). The records are stored in a suitable environment to prevent damage or deterioration and to prevent loss. **Records to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.** To accomplish the above, TNT EDM has developed, implemented and maintains a Quality Records Master List ([TNT-F-0006](#)), which lists the following information: Section or sub-section of the Quality Manual governing the application of the record, Description of Record, Location, Responsible (person/department), Retention Time, and Method of Disposal of the Records. (Hard copies are shredded and electronic copies are deleted.)

TNT-EDM, Inc., ensures that documents of external origin determined by TNT-EDM, Inc., to be necessary for the planning and operation of the quality management system are identified and their distribution controlled

Records that are created by and/or retained by Suppliers to TNT EDM are handled as follows:

- **Suppliers must forward a copy of the Quality Record to TNT EDM either by electronic means or Hard Copy, with Incoming shipments of products and/or services being procured.**
- **TNT EDM stores electronic copies of Quality Records within TNT EDM’s Computer Network System.**

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- **Hard Copy Quality Records received from Suppliers are scanned into a PDF file format and then stored within TNT EDM's computer Network system.**

All records will be made available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

Note: All retention time periods listed are deemed to be the "minimum" retention periods.
Note: The person/department listed as responsible is deemed to have the authority to retrieve the records (when required or deemed necessary to verify the effective operation of the Quality Management System) and they have the responsibility to ensure that the minimum retention periods are maintained.

TNT EDM shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by TNT EDM, but not less than two years from the date of product release by TNT EDM, or as specified by relevant Regulatory requirements.

Section 5

Management Responsibility

5.1 Management Commitment

TNT EDM Top Management shall provide evidence of its commitment to the development and implementation of the Quality Management System **and maintaining** and continually improving its effectiveness by:

- Communicating to all TNT EDM personnel, the importance of meeting customer as well as statutory and regulatory requirements. This is accomplished via the Advanced Product Quality Planning process and through ongoing communication of the Steering Committee monthly monitoring of TNT EDM's Key Business Measureables.
- Establishing the Quality Policy - the Quality Policy has been established, and communicated to all personnel via inclusion in a two hour seminar on ISO-9001:2000, **and follow up training session on the requirements for upgrade to include AS-9100B Additional Aerospace Requirements.**
- Ensuring that quality objectives are established via the formation of a Steering Committee whose members attended a two day seminar on Business Operating System (BOS) implementation; upon completion of which, each member of the Steering Committee was assigned a Key Business Measureable, with the

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responsibility of tracking, monitoring and reporting on progress of their assigned measureable at regularly scheduled monthly Steering Committee meetings.

- Conducting management reviews, augmented by formal monthly Steering Committee reviews of Key Business Measureables.
- Ensuring the availability of resources. Top Management is committed to allocate the resources required to maintain the effectiveness of the Quality Management System.

NOTE: For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.

5.2 Customer Focus

TNT EDM's Top Management shall ensure that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction. (See sections 7.2.1 Determination of requirements related to the product and 8.2.1 Customer Satisfaction).

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

5.3 Quality Policy

The President of TNT EDM has defined and documented its policy for quality, including objectives for its commitment to quality. The quality policy is relevant to TNT EDM's organizational goals and the expectations and needs of its customers. TNT EDM has communicated this policy to all personnel to ensure that this policy is understood, implemented and maintained at all levels of the organization.

Top Management shall ensure that the quality policy:

- Is appropriate to the purpose of TNT EDM
- Includes a commitment to comply with requirements, **maintain the effectiveness** and continually improve the effectiveness of the Quality Management System
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood within TNT EDM
- Is reviewed for continuing suitability – **this is part of "Annual" Management Review at years end; to determine whether there are any changes necessary to our Quality Policy**

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5.4 Planning

5.4.1 Quality Objectives

TNT EDM's Top Management shall ensure that quality objectives, including those needed to meet requirements for product, (see Section 7.1) are established at relevant functions and levels within TNT EDM. The quality objectives shall be measurable and consistent with the quality policy. To accomplish this requirement, TNT EDM has formed a formal Steering Committee, comprised of a cross-functional team of personnel representing the following: Quality System Manager, Project Managers, and CAD/SYS Administrator. Each member of the Steering Committee is the Champion of a Key Business Measurable (which is TNT EDM's method of identifying Quality Objectives). The champions have the responsibility to track, monitor and report on the progress of their Key Measurable at regularly scheduled monthly Steering Committee Meetings.

5.4.2 Quality Management System Planning

TNT EDM's Top Management ensures that:

- The planning of the Quality Management System is carried out in order to meet the requirements given in section 4.1, as well as the quality objectives
- The integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented

These requirements are met via the monthly Steering Committee review of Key Business Measurables, Internal Audit process and the Management Review process.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

TNT EDM's Top Management shall ensure that the responsibilities and authorities are defined, **documented** and communicated within TNT EDM.

TNT EDM's Top Management shall establish the interrelationship of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

NOTE: National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).

The above requirement is met via TNT EDM's Organization Chart and further augmented by

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the following Job Descriptions:

President/CEO

- Formulates the quality policy
- Provides the necessary resources to maintain and improve the effectiveness of the Quality Management System
- Prepares RFQs for punches, dies and general machining
- Prepares RFQs for Molds
- Verifies process capability and feasibility
- Provides customer liaison and service
- Handles customer complaints, concurring with Quality System Manager

Chief Financial Officer

- Controller of TNT EDM
- Treasury management
- Strategic Financial Planning (short & long term)
- Tax intermediary

Quality System Manager (Management Representative)

- Establishes and maintains the Quality Management System
- Reports to top management on the performance of the Quality Management System
- Audits implementation and effectiveness of the Quality Management System
- Serves as Internal Lead Auditor (planning, implementation, follow-up)
- Ensures review and disposition of Corrective Action Items from internal audits.
- Participates in advanced product quality planning
- Initiates requests for, and follows up with, corrective actions
- Coordinates continuous improvement process
- Coordinates and maintains document control activities
- Conducts measurement system evaluation studies
- Maintains and calibrates measuring and test equipment
- Performs inspections and testing

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- Handles non-conforming products
- Handles customer complaints, along with President
- Oversees control of Quality Records
- Administers, maintains and evaluates Customer Satisfaction Survey results
- Administers, maintains and evaluates Supplier Evaluations and Approved Supplier List

Manufacturing Department Leaders

- Supervise the activities of personnel in their department
- Assign work in the department consistent with established schedules and/or priorities
- Ensure all tasks within the department are performed as specified in procedures, work instructions and control plans
- Provide OJT training and guidance for personnel within the department as required by job descriptions and other procedures, etc...
- Ensure backup resources exist for tasks within the department
- Verify all gages, tools and fixtures are in good working order and verified against certified Gage Block and/or Standards
- Ensure all drawings, specifications and other operating standards are current and obsolete versions removed
- Performs individual manufacturing tasks as defined and required
- Ensure all products are manufactured to required specifications and within tolerances
- Ensure all preventative maintenance to be performed by department personnel are completed and documented as required

Project Managers

- Maintain communications interface with assigned customers on scheduling issues, changes, technical issues, quality concerns and customer satisfaction
- Ensure products are produced to acceptance requirements
- Prepare process control plans (Job Traveler) for prototype and production jobs
- Schedules production
- Input all projects, resources and priorities as needed to maintain the scheduling system and meet delivery objectives
- Monitor scheduling status and performance, changes in priorities, delays, etc. as required to maintain schedule integrity

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- Report scheduling performance, issues and concerns for management action
- Provides Manufacturing Control Plans/Setup Instructions
- Administrates stockroom
- Maintains JIT Inventory Levels to Meet Customer Needs

Office Manager

- Selects qualified suppliers from approved supplier list
- Prepares and approves purchasing documents
- Monitors and assesses supplier performance
- Prepares all Shipping and Delivery Information
- Ensures all Purchased Components and Materials meet specification requirements
- Establishes production work orders
- Receives purchased products
- Ensures purchased/stock material and product identification
- Ensures compliance with environmental regulations
- **Ensures compliance with environmental regulations**

5.5.2 Management Representative

TNT EDM 's top management has appointed the **Quality Systems Manager as the Management Representative** for **AS9100C/ISO 9001:2008, ISO – 13485:2003** and **(USNRC – 10 CFR Part 21)**. In this capacity, the Quality Systems Manager, irrespective of other responsibilities, has the responsibility and authority that includes:

- Ensuring that processes needed for the Quality Management System are established, implemented and maintained
- Reporting to top management on the performance of the Quality Management System and any need for improvement
- Ensuring the promotion of awareness of **regulatory and** customer requirements throughout TNT EDM
- **TNT EDM's Management Representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.**

5.5.3 Internal Communication

TNT EDM's top management shall ensure that appropriate communication processes are established within TNT EDM and that communication takes place regarding the effectiveness

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of the Quality Management System. This requirement is met via the Steering Committee members, who represent cross-functional departments and is communicated in the format of the BOS Meeting Agenda ([TNT-F-0010](#)) and through the communication of the Internal Audit process. In addition, all TNT EDM employees have an internal email account to maximize required communication.

5.6 Management Review

5.6.1 General

TNT EDM's top management shall review the Quality Management System at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the Quality Management System, including the quality policy and quality objectives. This requirement is met via a formal management review conducted on a yearly basis, which is further augmented by the monthly review of Key Business Measureables at the regularly scheduled monthly meetings of the Steering Committee.

5.6.2 Review Input

The input to management review includes information on:

- Results of audits - (both internal and external)
- Customer feedback – (including customer complaints)
- Process performance and product conformity – **this is accomplished via the review of chart data from the quality objectives established for each Key Business Metric being monitored and measured**
- Preventive and corrective actions – (review of corrective actions requests issued by either internal audits or external audits, and any changes to the Quality Management System necessary to prevent product or process nonconformity)
- Follow-up actions from previous management reviews – **(review of Open Action Items from the previous month BOS meeting for status update as to completion)**, and to verify that any actions as a result of the output from the previous management review have been completed
- Planned changes that could affect the Quality Management System – (these include both policy and procedural changes)
- Recommendations for improvement – Steering Committee members determine whether they need to champion additional Key Business Measureables or to raise the goal of existing Measureables
- Review of existing Quality Policy and Quality Objectives for suitability and effectiveness
- **New or revised regulatory requirements**

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5.6.3 Review Output

The output from the management review shall include any decisions and actions related to:

- Improvement **needed to maintain** the effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements
- Resource needs

Actions arising from the management review output are assigned to members of the Steering Committee for follow-up and implementation.

Section 6

Resource Management

6.1 Provision of Resources

TNT EDM shall determine and provide the resources needed to:

- Implement and maintain the Quality Management System (**maintain** and continually improve its effectiveness),
- Enhance customer satisfaction by meeting **regulatory and** customer requirements.

The provision of resources is determined based upon existing manufacturing capacity, current and future customer expectations, general economic conditions and projections, new technology to enhance production capacity and in general, TNT EDM's short and long term strategic planning.

6.2. Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. To meet this requirement, TNT EDM has developed and implemented a "Position Description" for each position within the organization. The position descriptions are detailed within Section 5.5.1 (Responsibility & Authority) within this Manual.

Note: Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.

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6.2.2 Competence, Training and Awareness

TNT EDM shall:

- **Determine the necessary competence for personnel performing work affecting conformity to product requirements,**
- **Where applicable, provide training or take other actions to achieve the necessary competence**
- **Ensure that the necessary competence has been achieved,**
- Evaluate the effectiveness of the actions taken
- Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- Maintain appropriate records of education, training, skills and experience

Note: National or Regional Regulations might require TNT EDM to establish documented procedures for identifying training needs.

Since the average tenure of TNT EDM's employees averages 15+ years working for TNT EDM, coupled with the fact that ALL personnel working within the Manufacturing, Assembly and Testing Processes are Skilled Tradesmen; Competence for personnel performing work affecting product quality is measured and determined by the Key Business Metrics being tracked such as: Rework Hours, Scrap Dollars, and On Time Delivery Performance, together with minimum Customer Complaints and no repetitive Customer Complaints for the same or similar issues.

If, and when, any negative trends occur in these Metrics, then a determination is made as to any additional on the job training which might be necessary in order to ensure compliance with Customer Requirements for the product being realized.

6.3 Infrastructure

TNT EDM shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements, including, as applicable:

- Buildings, workspace and associated utilities - TNT EDM has one of the most modern highest technological facilities in the world. The building and grounds are always well maintained. The workspace is kept in immaculate clean condition at all times.
- Process equipment (both hardware and software) - Preventive Maintenance schedules and checklists have been developed and implemented to ensure maximum uptime and efficiency.
- Supporting services (such as transport or communication) **or information systems** – TNT EDM has updated versions of Computer Aided Design (CAD), in order to maintain effective electronic communication with its customers.

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TNT EDM shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained.

The above requirement is addressed under Clause 7.5.1 (Control of Production and Service Provision) The use of suitable equipment – TNT EDM has the most modern and advanced manufacturing & process equipment. All equipment in use is “state of the art” technology. In addition, in order to maximize equipment uptime, TNT EDM has developed and implemented a Preventive Maintenance Process, which is governed under work instruction “Preventive Maintenance Process” as detailed in ([TNT-WI-0009](#)) including a Machine PM Schedule ([TNT-F-0013](#)), for each type of manufacturing equipment in use.

6.4 Work Environment

TNT EDM shall determine and manage the work environment needed to achieve conformity to product requirements. This requirement is met by factoring in Personnel Safety and Cleanliness of Premises. To augment this, the following work instructions have been developed and implemented: “Power Lock Out” ([TNT-WI-0002](#)), “Hazardous Material Communication” ([TNT-WI-0003](#)) and “Safety & Housekeeping” ([TNT-WI-0004](#)).

In addition, the entire TNT EDM facility is a temperature controlled environment with thermostats under locked control whereby only designated personnel have access to the key for any necessary adjustments to the temperature control.

The following requirements shall apply:

- TNT EDM shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).
- If work environment conditions can have an adverse effect on product quality, TNT EDM shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).
- TNT EDM shall ensure that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person (see 6.2.2 b).
- If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).

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Note: The term work environment relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).

Section 7

Product Realization

7.1 Planning of Product Realization

TNT EDM shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System. In planning product realization, TNT EDM shall determine the following, as appropriate:

- Quality objectives and requirements for the product. This is accomplished in the quote stage, via the requirements for determination and review of requirements related to product (see 7.2.1, 7.2.2 & 7.2.3).

NOTE: Quality objectives and requirements for the product include consideration of aspects such as

- i. Product and personal safety,**
 - ii. Reliability, availability and maintainability,**
 - iii. Producibility and inspectability,**
 - iv. Suitability of parts and materials used in the product,**
 - v. Selection and development of embedded software, and**
 - vi. Recycling or final disposal of the product at the end of its life.**
- The need to establish processes **and** documents and **to** provide resources specific to the product. This is accomplished through advanced product quality planning process and by determination of the proper equipment, tooling and qualification of personnel to perform the process events.
 - Required verification, validation, monitoring, **measurement**, inspection and test activities specific to the product and the criteria for product acceptance. This is also driven by the advanced product quality planning process. The output of this planning activity is the generation of either of the two documents (based upon the product commodity) which serve as the combination Control Plan and Work Instruction.

The Job Traveler includes all pertinent information including the operations to be performed.

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The Job Traveler Form is used for all other product commodities; and it is computer generated via the computer software program. It includes all pertinent data including sequence of process operations, Inspections requirements, etc.

In both cases as identified above, this combination Control Plan/Work Instruction travels with the product together with the drawing(s) in a clear plastic Job Folder.

- Records needed to provide evidence that the realization processes and resulting product meets requirements. All records are maintained in accordance with the requirements for Control of Quality Records (see 4.2.4).
- Configuration management appropriate to the product;
- The identification of resources to support the use and maintenance of the product. This is accomplished via our Job Traveler (TNT-WI-0016 "Production Job Creation and Monitoring in VISTA"), which describes each process operation, specifications and signatory evidence of completion of process steps to verify that product requirements have been met.

TNT EDM shall establish documented requirements for risk management throughout product realization. Records arising from Risk Management shall be maintained (see 4.2.4)

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2: TNT EDM may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 Project Management

As appropriate to TNT EDM and the product, TNT EDM shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

The organization shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product.

- a) assignment of responsibilities for risk management,
- b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
- c) identification, assessment and communication of risks throughout product realization,

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- d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
- e) acceptance of risks remaining after implementation of mitigating actions.

7.1.3 Configuration Management

TNT EDM has established, implemented and maintains a Configuration Management Process that includes, as appropriate to the products which we manufacture.

- A) configuration management planning,
- B) configuration identification,
- C) change control,
- D) configuration status accounting, and
- E) configuration audit.

NOTE: See ISO 10007 for guidance

The following describes the process of how we apply Configuration Management Requirements, as appropriate and/or required, are:

- Design and Development controls, including change control
- Document and Data Control, including change control
- Manufacturing and Assembly Controls, including change controls
- Determination of Change incorporation/effectivity
- Product Identification and Traceability (including that for components and constituent parts)
- Material Identification and Traceability
- 1st Production Article Inspection (“FAI”)
- Quality Records Control

The Following Configuration Tools are used, as appropriate and/or required:

- Drawings, specifications
- Routers, travelers
- Bills of Material, Where-Used listings
- Inspection and 1st Article reports/records
- CM process description and written procedures
- Manufacturing, Assembly and Inspection plans and W/Is
- Nonconforming product documents (including concessions, waivers)
- Design, Product and Process change requests / notices
- Document and Data change requests / notices

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7.1.4 Control of work transfers

TNT has established, implemented and maintains a process to plan and control the temporary or permanent transfer of work (e.g. from one organization facility to another, from the organization to a supplier, from one supplier to another supplier" and to verify the conformity of the work to requirements.

7.2. Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

TNT EDM shall determine:

- 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
- Statutory and regulatory requirements applicable to the product
- Any additional requirements **considered necessary**, by TNT EDM

To meet the above requirements TNT EDM has developed and implemented the following work instructions:

- Proposal Quotation Process ([TNT-WI-0005](#)) – for Dies & Punches
- Proposal Preparation Process ([TNT-WI-0006](#)) for Molds

NOTE: Requirements related to the product can include special requirements.

Note: Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of Requirements Related to the Product

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

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

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7.1.2)

Records of the results of the review and actions arising from the review are maintained in accordance with the requirements of section 4.2.4. Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by TNT EDM prior to acceptance. These requirements are met via the same work instructions as listed above ([TNT-WI-0005](#) & [TNT-WI-0006](#)) and further augmented by the process of comparing the original quotation sent with the contract or order received from the customer.

7.2.3 Customer Communication

TNT EDM shall determine and implement effective arrangements for communicating with customers in relation to:

- Product information being handled by the appropriate Engineering and/or Project Managers assigned to the product
- Inquiries, contracts or order handling, including amendments, are handled in accordance with the contract review process governed by work instructions as identified above ([TNT-WI-0005](#) & [TNT-WI-0006](#))
- Customer feedback, including customer complaints. Customer feedback in the way of Customer Survey information and/or Customer Complaints, are handled by the appropriate Engineer, Project Manager (assigned to the product) and the Quality System Manager for presentation as a part of the Management Review Input process
- **Advisory notices (see 8.5.1)**

Note: The majority of customer communications are handled electronically via Internet and/or CAD/CAM processes, which in turn, furnishes TNT EDM with a record of the communication for traceability.

7.3 Design and Development

7.3.1 Design and Development Planning

TNT EDM has established the following as the documented procedures for Design and Development:

TNT EDM shall plan and control the design and development of product. During the design and development planning, TNT EDM shall determine:

- The design and development stages – When required by the customer, TNT EDM develops a tool timing chart, showing detailed timing for each milestone event of the design and build process. The timing chart includes as appropriate: Approval of Data, Preliminary Design, Order Steel/Materials, Final Design, Cutter Paths, General Machining, CNC Machine Steel, Heat Treat Process, Mold Base completion, finish Steel / Grind, CNC Electrodes, CNC EDM, Wire EDM, Fit Spot, Assemble and Mold

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Delivery.

- **(In respect of TNT EDM task sequence, mandatory steps, significant stages and method of configuration control.)**
- The review, verification, validation **and Design Transfer activities** that are appropriate to each design and development stage - These activities are accomplished via a Concept and Preliminary Line Up meeting with the customer involved; and are further detailed in the CAD/CAM Processes work instruction ([TNT-WI-0028](#)).
- The responsibilities and authorities for design and development. All responsibilities and authorities are in the Engineering Department with the General Manager having the final authority for Design and Development processes.
- **Where appropriate, TNT EDM shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.**

The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

TNT EDM shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be **documented and** updated, as appropriate, as the design and development progresses. To accomplish the above requirement, TNT EDM has developed and implemented the CAD/CAM Mold Processes work instruction ([TNT-WI-0028](#)), which governs the following areas:

- Preparing the Part Data
- Importing 2-D Mold Design
- Creating the Reference Data
- Creating the 3-D Mold Design
- Electrode Design
- Generating Cutter Paths.

NOTE: Design Transfer Activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

Note: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination as suitable for the product and TNT-EDM.

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7.3.2 Design and Development Inputs

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

These inputs shall include:

- Functional, performance **and safety** requirements **according to the intended use**
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development
- **Output(s) or risk management (see 7.1)**

These inputs shall be reviewed for adequacy **and approved.**

Requirements shall be complete, unambiguous and not in conflict with each other.

All of the criteria for Design and Development Inputs are derived from the following sources:

- Customer Purchase Order Requirements
- Customer Mold / Tooling Standards
- Industry Standards
- TNT EDM past experience with products of a similar nature

7.3.3 Design and Development Outputs

The outputs of design and development shall be provided in a form **suitable for** verification against the design and development input and shall be approved prior to release. Design and development outputs shall:

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

TNT shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained; including for example:

- **The drawings, part lists, and specifications necessary to define the configuration and the design features of the product, and**
- **The material, process, manufacturing and assembly data needed to ensure**

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conformity of the product.

Note: Information for production and service provision can include details for the preservation of product.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements:

- To evaluate the ability of the results of design and development to meet requirements
- To identify any problems and propose necessary actions
- **To authorize progression to the next stage**

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1).

Records of the results of the reviews and any necessary actions shall be maintained.

TNT EDM conducts the following Design and Development Reviews: Concept (Line-Up meeting), Preliminary Design Review, 50% Design completed Review and 100% Final Design Review. These reviews are conducted with the customer involved and the output of the reviews is customer sign-off/approval of the review stage being conducted.

7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and Development Validation

- Design and Development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practical, validation shall be completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions shall be maintained (see 4.2.4).

As a part of design and development validation, TNT EDM shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by regional regulations.

NOTE 1 – If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been

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formally transferred to the customer.

NOTE 2 – Provision of medical devices for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.

7.3.6.1 Design and development verification and validation testing

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed and documented to ensure and prove the following:

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

7.3.6.2 Design and development verification and validation documentation

At the completion of design and/or development, TNT EDM ensures that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.7 Control of Design and Development Changes

Design and Development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approve before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and already delivered product. Records of the results of the review of changes and any necessary actions shall be maintained. Design and Development changes are identified in either of the following ways:

- During the Design and Development stages, drawings may be marked up to reflect changes as the design evolves
- Customer change request form
- Customer Final Design approval

Design and development changes shall be controlled in accordance with the confirmation management process (see 7.1.3).

Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

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7.4 Purchasing

7.4.1 Purchasing Process

TNT EDM shall ensure that purchase product conforms to specified requirements. The type and extent of control applied to the supplier and the purchase product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. TNT shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer. TNT EDM shall evaluate and select suppliers based on their ability to supply products in accordance with TNT EDM's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. To accomplish this, TNT EDM has developed and implemented an "Approved Supplier List" ([TNT-F-0021](#)), which lists the major suppliers of Raw Materials (Steel, etc.), Outsource Services (Machining, Heat Treat, Plating) and Component Parts (Cylinders, Hydraulics, Pneumatics, etc.). All suppliers on the list are sent a Supplier Development Form ([TNT-F-0003](#)), which requests the supplier to identify the current status of their Quality Management System. Any supplier used who is registered to the current version of ISO-9000, by an independent third party certification body/registrar, is deemed to have met TNT EDM's criteria selection process and accordingly, is placed on the Approved Supplier List. The criteria for the selection of New Suppliers to be added to the Approved Supplier List is governed by work instruction "Purchasing Process and Supplier Development Control Processes" (TNT-WI-0028). In the event that product received from an Approved Supplier is rejected more than three instances within a 90 day period of time, the supplier is placed on probation and further, is required to submit to TNT EDM written corrective and preventive action that will be taken in order to prevent recurrence of product related quality issues. Suppliers who have been placed on probation must demonstrate conformance to TNT EDM's quality and delivery requirements for a period of six months before they can be taken off probation and listed in good standing of the Approved Supplier List.

NOTE: One factor that can be used during supplier selection and evaluation is supplier quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, organization approvals from government authorities). Use of such data would be only one component of an organization's supplier control process and the organization remains responsible for verifying that purchased product meets specified purchase requirements.

TNT EDM maintains the following:

- A register of its Suppliers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
- Periodically review Supplier performance; the results of these reviews as a basis for establishing the level of controls to be implemented

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- Defines the necessary actions to take when dealing with Suppliers that do not meet requirements
- Ensure where required that both TNT EDM and all Suppliers use customer-approved special process sources
- Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status, and
- Determine and manage the risk when selecting and using suppliers (see 7.1.2).

The Approved Supplier List is validated as to the Supplier status, on an annual basis; and updated as appropriate.

7.4.2 Purchasing Information

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

- Requirements for approval of product, procedures, processes and equipment,
- Requirements for qualification of personnel,
- Quality Management System requirements,
- The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data.
- Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,
- Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,
- Requirements regarding the need for the supplier to
 - Notify TNT EDM of nonconforming product,
 - Obtain TNT EDM's approval for nonconforming product disposition,
 - Notify TNT EDM of changes in product and/or process, changes of suppliers, change of manufacturing facility location and, where required, obtain TNT EDM's approval, and
 - Flow down to the supply chain the applicable requirements including customer requirements,

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- Records retention requirements, and,
- Right of access by TNT EDM, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

Any/all authorized personnel requesting to purchase raw materials, outsource services and/or component parts to be integrated into TNT EDM's product or process, must fill out the Purchasing Requisition Form ([TNT-F-0018](#)) and submit it to the office manager for processing.

TNT EDM shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. Upon completion of the information listed on the Purchasing Requisition Form, the office manager will enter the data in the data base and issue an appropriate purchase order number to the supplier.

To the extent required for traceability given in 7.5.3.2, TNT EDM shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

7.4.3 Verification of Purchased Product

TNT EDM shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. To meet this requirement, TNT EDM has developed and implemented the following work instructions for receiving inspection:

- Receiving Inspection – Specialty Items ([TNT-WI-0007](#))
- Receiving of Job Material and Components ([TNT-WI-0008](#))

NOTE 1: Customer verification activities performed at any level of the supply chain should not be used by the organization or the supplier as evidence of effective control of quality and does not absolve the organization of its responsibility to provide acceptable product and comply with all requirements.

NOTE 2: Verification activities can include

- Obtaining objective evidence of the conformity of the product from the supplier (e.g., accompanying documentation, certificate of conformity, test records, statistical records, process control records).
- Inspection and audit at the supplier's premises,
- Review of the required documentation,
- Inspection of products upon receipt, and
- Delegation of verification to the supplier or supplier certification.

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and

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replacement if it is subsequently found that the product does not meet requirements.

Where TNT EDM delegates verification activities to the supplier, the requirements for delegation is defined and a register of delegations maintained.

Where TNT EDM or its customer intends to perform verification at the supplier's premises, TNT EDM states the intended verification arrangements and method of product release in the purchasing information.

Records of the verification shall be maintained (see 4.2.4).

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

TNT EDM shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- The availability of information that describes the characteristics of the product, accomplished by any of the following:
 - Electronically controlled customer job files by part number is governed under work instruction “Punch & Die File Control” ([TNT-WI-0010](#)) and “Mold File Control” ([TNT-WI-0011](#)),
 - Job Traveler serves as a combination Control Plan / Work Instruction.
 - NOTE: See section 7.1 Planning for Product Realization

NOTE: This information can include drawings, parts lists, materials and process specifications.

- The availability of **documented procedures, documented requirements**, work instructions, **reference materials and reference measurement procedures** as necessary. TNT EDM has developed and implemented detailed work instruction for all employees having responsibilities for the operation of processes that have any affect on product quality. All work instructions are available at the work station (point of use for the process), either in hard copy form or via electronic access to the process performer. See Master List Document Control ([TNT-F-0002](#)) for a list of all Work Instructions utilized within the Quality Management System.

NOTE: Work Instructions can include process flow charts, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards) and inspection documents.

- The use of suitable equipment – TNT EDM has the most modern and advanced manufacturing & process equipment. All equipment in use is “state of the art” technology. In addition, in order to maximize equipment uptime, TNT EDM has developed and implemented a Preventive Maintenance Process, which is governed under work instruction “Preventive Maintenance Process” as detailed in ([TNT-WI-](#)

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[0009](#)) including a Machine PM Schedule ([TNT-F-0013](#)), for each type of manufacturing equipment in use.

NOTE: Suitable equipment can include product specific tools (e.g., jugs, fixtures, molds) and software programs.

- The availability and use of monitoring and measuring **Equipment** – All TNT EDM's equipment is CNC Programmed. In addition, in-process inspection measuring devices (reference gages) are checked against Gage Blocks, which are certified via TNT EDM's CMM. Final inspection on all finished dimensions, including special characteristics, when applicable, are performed on TNT EDM's CMM, which is certified by a qualified outside source once per year.
 - The implementation of monitoring and measurement– TNT EDM's Control Plan (Job Traveler) identifies the process sequences. The drawing, which travels with the Control Plan, identifies the characteristics to be monitored and measured. Employees performing in-process inspections, records the measurement taken on the control plan and final inspection reports are in the form of CMM print out reports.
 - The implementation of **product** release, delivery and post-delivery activities – Production is scheduled in order to meet customer requirements, such as just-in-time (when applicable), is supported by TNT EDM's software system, which permits access to production information at key stages of the process and is order driven. In addition, TNT EDM has developed and implemented a work instruction "Job Scheduling Process" ([TNT-WI-0012](#)), which governs this process.
 - **TNT EDM maintains accountability for all product during production (e.g., parts quantities, split orders, nonconforming product).**
 - **TNT EDM provides evidence that all production and inspection/verification operations have been completed as planned or as otherwise documented and authorized. This is accomplished via our Job Traveler.**
 - **TNT EDM ensures provision for the prevention, detection and removal of foreign objects.**
 - **TNT EDM ensures monitoring and control of utilities and supplies (e.g., water, compressed air, electricity and chemical products) to the extent they affect conformity to product requirements, and**
 - **TNT EDM has established criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations).**
 - **The implementation of defined operations for labeling and packaging.**
- TNT EDM shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.**

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NOTE: A batch can be a single medical device.

Planning shall consider, as applicable,

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
- Designing, manufacturing and using tooling to measure variable data,
- Identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
- Special processes (see 7.5.2).

7.5.1.1 – Production Process Verification

TNT EDM shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

NOTE: This activity is often referred to as first article inspection.

7.5.1.2 Control of production process changes

- TNT EDM manufacturing personnel are authorized to approve changes to production processes identified as needed to ensure on time delivery and/or product conformity, when these instances occur the manufacturing personnel must date and initial the Job Traveler with the change that is being made, and will verbally notify the Quality Manager or Project Manager, as appropriate.
- TNT EDM shall control and document changes affecting processes, production equipment, tools or software programs.
- Documented procedures and/or work instructions are available via Software Computer stations throughout each Manufacturing department to control their implementation.
- The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.2 – Control of Production and Service Provision – Specific Requirements:

7.5.1.2.1 – Cleanliness of product and contamination control:

TNT EDM shall establish documented requirements for cleanliness of product if

- Product is cleaned by TNT EDM prior to sterilization and/or its use,
- Product is supplied non-sterile to be subjected to a cleaning process prior to

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sterilization and/or its use,

- Product is supplied to be used non-sterile and its cleanliness is of significance in use,
- Process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.

7.5.1.2.2 - Installation Activities:

If appropriate, TNT EDM shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.

If agreed, customer requirements allow installation to be performed by someone other than TNT EDM or its authorized agent, TNT EDM shall provide documented requirements for installation and verification.

Records of installation and verification performed by TNT EDM shall be maintained (see 4.2.4).

7.5.1.2.3 Servicing Activities:

If servicing is a specified requirement, TNT EDM shall establish documented procedures, work instructions, reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.

Records of servicing activities carried out by TNT EDM shall be maintained (see 4.2.4).

NOTE: Servicing can include, for example, repair and maintenance.

7.5.1.3 Particular Requirements for Sterile Medical Devices:

TNT EDM shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).

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, shall be validated prior to release for production and shall be maintained.
- Storage requirements, including periodic preservation/condition checks, are defined for production equipment or tooling in storage.

7.5.1.4 Post-delivery Support

Post-delivery support shall provide as applicable for the

- collection and analysis of in-service data,

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- **Actions to be taken, including investigation and reporting, when problems are detected after deliver,**
- **Control and updating of technical documentation,**
- **Approval, control and use of repair schemes, and**
- **Controls required for off-site work (e.g., TNT EDM's work undertaken at the customer's facilities).**

7.5.2 Validation of Processes for Production and Service Provision

TNT EDM shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, **and as a consequence**, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. Validation of all processes and product is broken down into the following specific categories: Design Validation, Receiving Inspection of Incoming Materials, Component Parts, and/or Outsourced services such as machining, Heat Treat, Plating, etc., In-Process Inspections and Final Inspections (Try-out process for Molds).

NOTE: These processes are often referred to as special processes.

TNT EDM shall establish arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes –The criteria for all of TNT EDM products is specified on the drawing and on the Job Traveler (Control Plan) and Customer Buy-off (Molds). TNT EDM has developed and implemented work instructions governing all of the above criteria as listed on Master List Document Control Work Instructions ([TNT-F-0002](#)). If any of the inspections and/or tests fail, the procedure for Control of Nonconforming Product under Section 8.3 is initiated.
- Approval of equipment and qualification of personnel – The equipment criteria is specified on the Control Plan by sequence of operations and the qualification of personnel is governed under the process for competence, awareness and training, as detailed in (Section 6.2.2).
- Use of specific methods and procedures – The criteria is met via the detailed work instructions which have been developed and implemented for all employees performing work which can affect product quality.
- Requirement for records – The process is governed under the procedure for Control of Records in section 4.2.4 of this manual. Unique validation records are in the following formats:
 - Job Traveler – Employees record the dimensional result of the inspections/tests which they perform
 - Try-out (Molds) – The customer signed buy-off is the validation that the Molds have passed all required inspections/tests

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- CMM print out – The validation that dies, punches and electrodes have passed all required inspections/tests
- Revalidation – If any in-process and/or final inspections/tests fail so that the product can be reworked, the product will be revalidated after rework; according to the above defined process.

TNT EDM shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

Records of validation shall be maintained (see 4.2.4).

7.5.2.2 – Particular Requirements for Sterile Medical Devices:

TNT EDM shall establish documented procedures for the validation of sterilization processes.

Sterilization Processes shall be validated prior to initial use.

Records of validation of each sterilization process shall be maintained (see 4.2.4).

7.5.3 Identification and Traceability

Where appropriate, TNT EDM shall identify the product by suitable means throughout product realization. **Including maintaining the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration and shall establish documented procedures for such product identification, as follows:** TNT EDM shall identify the product status with respect to monitoring and measurement requirements **throughout product realization,** including **when acceptance authority media are used (e.g., stamps, electronic signatures, passwords), TNT EDM has established and documents controls for the media.** Where traceability is a requirement, TNT EDM shall control the unique identification of the product **and maintain records,** including according to the level of traceability required by **contract, regulatory or other established requirement.**

NOTE: Traceability requirements may include

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

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- **For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.**

The following methods of identification and traceability are utilized:

- The control plan (Job Traveler) identifies the product with the TNT EDM Job Number, Customer Part Number, Drawing and Rev. Number.
- The Software system identifies the location of the product in process.
- Punches and Dies – ALL punches and dies have an individual serial number.
- Inspection Status – All product that has passed final inspections/tests are marked with a “BLUE” marker.
- Rework items – If, during processing, any rework is required, the product is identified with a “BLACK” marker.
- Nonconforming or Suspect product – Identified with a “RED” marker and moved to a quarantine area pending disposition.
- General notations can be marked with a “GREEN” marker.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 7.1.3).

7.5.3.1 – Identification:

TNT EDM shall establish documented procedures to ensure that medical devices returned to TNT EDM are identified and distinguished from conforming product (see 6.4 d).

7.5.3.2 – Traceability

7.5.3.2.1 – General:

TNT EDM shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).

7.5.3.2.2 – Particular Requirements for active implantable medical devices and implantable medical devices in defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.

The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection.

Records of the name and address of the shipping package consignee shall be maintained.

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7.5.3.3- Status Identification –

TNT EDM shall identify the product status with respect to monitoring and measurement requirements.

The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer Property

TNT EDM shall exercise care with customer property while it is under our control or being used by TNT EDM. The method of control is: to identify, verify, protect and safeguard customer property provided for use of incorporation into the product.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, TNT-EDM shall report this to the customer and maintain records (see 4.2.4).

NOTE: Customer property can include intellectual property or confidential Health information, and personal data. The process for customer property is governed by the work instruction “Processing Customer Property” ([TNT-WI-0024](#)).

7.5.5 Preservation of Product

TNT-EDM shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection.

Preservation shall also apply to the constituent parts of a product.

TNT EDM addresses the above requirements in the following manner:

- Identification – all product manufactured is identified with a Job Number, corresponding part number, and serial numbers (when applicable).
- Handling – all product is handled by either Hi-lo truck, hand carts (with product placed on hand carts in such a manner that finished surfaces cannot be damaged).
- Packaging – requirements are considered based upon surface finish and tolerances of the product. TNT EDM utilizes their expertise in determining the appropriate packaging process deemed necessary to protect the product during shipment to the customer. (i.e., Tight tolerance work with exposed teeth is wax or rubber coated, core rods are packaged in individual cardboard containers, etc.)
- Storage – Steel is stored in storage racks, Graphite is stored in an appropriate area and labeled according to size, Electrode Holders are stored in a designated area marked “3R”, finished product inventory is stored in a designated area and identified by Part Number for JIT processing, mold component parts are stored in appropriate cabinets and identified.

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- Protection – all material and/or product stored and/or inventoried is protected in order to preserve the material or inventoried product for its intended application or use.
- **TNT EDM shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4).**

Preservation of product also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, 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.**

7.6 Control of Monitoring and Measuring Equipment

TNT EDM shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

TNT EDM maintains a register of these monitoring and measuring equipment and defines the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Note: Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

TNT EDM shall establish processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements, **including ensuring that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.**

Where necessary, to ensure valid results, measuring equipment shall:

- Be calibrated or verified, **or both**, at specified intervals, or prior to use, 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 (see 4.2.4)
- Be adjusted or re-adjusted as necessary
- **Have identification in order to determine its** calibration status

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- Be safeguarded from adjustments that would invalidate the measurement result
- Be protected from damage and deterioration during handling, maintenance and storage.

TNT EDM shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, TNT EDM shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. TNT EDM shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

The above requirements are met in the following manner at TNT EDM:

- A Master List of monitoring and measurement devices deemed necessary has been developed and is maintained.
- All Hand-held gages, which do not require a set-up are used for "Reference" only. These reference gages are checked prior to each use or application against the Standard Gage Blocks, which are certified by the CMM, on a semi-annual basis.
- The CMM is certified by a qualified outside source on an annual basis.
- Due to the hi-tech nature of TNT EDM's products all having tight tolerances, all gages used in-process are handled with due care and safeguarded from adjustments and protected from damage and deterioration during handling, maintenance and storage.

Note: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

Section 8 Measurement, Analysis and Improvement

8.1 General

TNT EDM shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate conformity **to product requirements**,
- Ensure conformity of the Quality Management System, and

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- Continually improve the effectiveness of the Quality Management System

This shall include determination of applicable methods, including statistical techniques and the extent of their use.

Note: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- Design verification (e.g., reliability, maintainability, safety),
- Process control,
 - Selection and inspection of key characteristics,
 - Process capability measurements,
 - Statistical process control,
 - Design of experiment,
- Inspection – matching sampling rate to the criticality of the product and to the process capability, and
- Failure mode, effect and criticality analysis.

NOTE: National or Regional Regulations might require documented procedures for implementation and control of the application of statistical techniques.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the Quality Management System, TNT EDM shall monitor information relating to customer perception as to whether TNT EDM has met customer requirements. The methods for obtaining and using this information are determined in the following manner:

- Repeat and increased business from existing customer base
- New business opportunities derived from TNT EDM's reputation for quality, as communicated by existing customers
- Minimal number of customer complaints
- Minimal number of customer returns
- Above average ratings from customers on TNT EDM's Customer Satisfaction Survey form ([TNT-F-0014](#))

TNT EDM shall establish a documented procedure for a feedback system (see 7.2.3 c) to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 & 8.5.3).

If National or Regional Regulations require TNT EDM to gain experience from the post-production phase, the review of this experience shall form part of the feedback system

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(see 8.5.1).

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. TNT EDM shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

Note: Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, and dealer reports.

8.2.2 Internal Audit

TNT EDM shall conduct internal audits at planned intervals to determine whether the Quality Management System:

- Is effectively implemented and maintained
- Conforms to the planned arrangements to the requirements of the International Standard and to the Quality Management System requirements established by TNT EDM

NOTE: Planned arrangements include customer contractual requirements.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

The following is the procedure for the deployment of the Internal Audit Process:

An audit program^{me} is planned by 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 shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. TNT EDM has established an Internal Audit schedule ([TNT-F-0015](#)), which includes all Processes being scheduled for the audits and links all the Clauses of **AS9100C/ISO 9001:2000**; **ISO-9001:2008**, **ISO – 13485:2003** and **(USNRC – 10 CFR Part 21)** and will be updated on an annual basis. In addition, a cross-functional team of three personnel have successfully completed a two-day seminar on Internal Auditing to ISO 9001:2000, **and update training to include the changes to ISO 9001:2008, together with**

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additional requirements for ISO 13485:2003. To ensure objectivity and impartiality of the audit process, an Internal Auditor Independence Matrix ([TNT-F-0016](#)) has been established and implemented, which clearly identifies the sections of the Standard which each individual internal auditor is excluded from participating in the audit process.

Records of the audits and their results shall be maintained (see 4.2.4).

TNT EDM also may reserve the right to outsource the Internal Audit Process to qualified consultants who have been certified by the Registrar Accreditation Board (RAB), as Lead Auditors. In the event that this option is exercised, it will be the responsibility of the contract Lead Auditor to develop the audit plan, conduct the internal audit, report on the findings of the audit, issue Corrective Action Requests (CAR) when deemed necessary and shall have the responsibility for closure of any CAR's issued. TNT EDM has appointed one of the above trained Internal Auditors as the Lead Internal Auditor, who has the responsibility for developing the audit plan(s) for each of the internal auditors, ensuring that the internal audits are conducted according to the established schedule, reporting on the results of the audit at management review and maintaining records of the audits for a minimum of three years.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. The time period for closure is not to exceed 30 days for implementation of corrective and preventive actions. Follow-up audit activities shall include the verification of the actions taken being effective and the reporting of the verification results (see 8.5.2).

NOTE: See ISO 19011 for guidance.

8.2.3 Monitoring and Measurement of Processes

TNT EDM shall apply suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. These methods shall demonstrate the ability of the processes to achieve planned results. **When planned results are not achieved, correction and corrective action shall be taken, as appropriate.** TNT EDM determines the effectiveness of the Quality Management System by the monthly Steering Committee Reviews of progress towards goals established for Key Business Measureables, Internal Audit Processes and Management Review processes.

NOTE: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

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In the event of process nonconformity, TNT EDM takes the following actions:

- Take appropriate action to correct the nonconforming process,
- Evaluate whether the process nonconformity has resulted in product nonconformity,
- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- Identify and control any nonconforming product (see 8.3).

8.2.4 Monitoring and Measurement of Product

TNT EDM shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the Product Realization Process in accordance with the planned arrangements (see 7.1). **Evidence of conformity with the acceptance criteria shall be maintained.**

Measurement requirements for product acceptances shall be documented and shall include

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- Required records of the measurement results (at a minimum, indication of acceptance or rejection), and
- Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified TNT EDM shall ensure they are monitored and controlled in accordance with the established processes.

When TNT EDM uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Were product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

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When required, the plan is submitted for customer approval.

TNT EDM ensures that product is held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

This requirement is met via the following: defined criteria for review and approval of the processes; the criteria for all of TNT EDM products are specified on the drawing and on the Job Traveler (Control Plan) and Customer Buy-off (Molds). TNT EDM has developed and implemented work instructions governing all of the above criteria as listed on Master List Document Control Work Instructions ([TNT-F-0002](#)). If any of the inspections and/or tests fail, the procedure for Control of Nonconforming Product under Section 8.3 is initiated.

Requirement for records – The process is governed under the procedure for Control of Records in section 4.2.4 of this manual. Unique verification records are in the following formats:

- Try-out (Molds) – The customer signed buy-off is the validation that the Molds have passed all required inspections/tests.
- CMM print out – The verification that dies, punches and electrodes have passed all required inspections/tests.

Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4)

TNT EDM ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices

The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.

8.3 Control of Nonconforming Product

TNT EDM shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. **A documented**

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procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

NOTE: The term "nonconforming product" includes nonconforming product returned by a customer.

TNT EDM's documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, TNT EDM shall deal with nonconforming product by one or more of the following ways:

- Taking action to eliminate the detected nonconformity
- Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- Taking action to preclude its original intended use or application
- **By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started**
 - i. TNT EDM's nonconforming product control process shall provide for timely reporting of the delivered nonconforming product; NOTE: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.
- By taking actions necessary to contain the effect of the nonconformity on other processes or products.

Dispositions of use-as-is or repair shall only be used after approval by an authorized representative of the organization responsible for design.

NOTE: Authorized representative includes personnel having delegated authority from the design organization.

TNT EDM shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

TNT EDM shall ensure that nonconforming product is accepted by concession only if Regulatory Requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).

TNT EDM has established and maintains the following documented procedure to ensure that product that does not conform to specified requirements is prevented from unintended use or application. This control provides for identification, documentation, evaluation, segregation, (when practical), disposition of nonconforming product and for notification to the functions concerned.

The responsibility for review and authority for the disposition of nonconforming product is

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limited to the Quality Department; **who have the responsibility for review and authority for the disposition of nonconforming product. The process for approving personnel making these decisions is based upon their respective duties as defined within the respective Job Descriptions. Nonconforming product is reviewed in accordance with documented procedures and work instruction ([TNT-WI-0029](#)).**

It may be:

- Reworked to meet the specified requirements. If during processing, product is determined to be nonconforming to specification requirements, but it is determined that the product can be reworked, the product is marked with a BLACK Marker. Once the rework is completed and the product is re-inspected, the BLACK Marking is removed.
- Accepted with or without repair by concession. If it is determined that the nature of the nonconformity will not affect form, fit and/or function, it may be processed. In appropriate situations, the customer may be contacted to authorize the product to be used as is.
- Re-graded for alternative applications - Graphite may be used for other job applications.
- Rejected or scrapped
- **When nonconforming product is corrected it shall be subject to reverification to demonstrate conformity to the requirements.**
- Records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

TNT EDM ensures that product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

If product needs to be reworked (one or more times), TNT EDM shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented. (see 4.2.3 & 7.5.1).

8.4 Analysis and Use of Data

TNT EDM shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The primary method of satisfying the requirement, is by evaluating the progress towards established goals of Key Business Measureables, which are presented during regularly scheduled monthly Steering Committee meetings together with the Management Review Process.

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The analysis of data provides information relating to:

Feedback (see 8.2.1)

- Customer satisfaction (see 8.2.1) – This is accomplished via a review of the responses to TNT EDM's Customer satisfaction survey, together with a review of the number of customer complaints (customer dissatisfaction).
- Conformance to product requirements **(See 8.2.4)** – This is accomplished via a review of customer complaints, scrap reports and analysis of rework on a monthly basis.
- Characteristics and trends of processes and products including opportunities for preventive action **(see 8.2.3 and 8.2.4)**, – This is accomplished via benchmarking data together with ongoing monthly review of TNT EDM's Key Business Measureables and from the Internal Audit process results.
- Suppliers **(See 7.4)** – This is accomplished via tracking on-time delivery and quality performance of TNT EDM's major suppliers of raw materials, outsourced services and component parts.

Records of the results of the analysis of data shall be maintained (see 4.2.4).

8.5 Improvement

8.5.1 Continual Improvement

TNT EDM shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the Quality Management System.

TNT EDM shall continually improve the effectiveness of the Quality Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. This is determined by an evaluation of the results of the above identified items. Particular information identifying opportunities for improvement is by the ongoing tracking, monitoring, reporting and evaluation of TNT EDM Key Business Measureables. If any of the Key Business Measureables do not show steady progress, or if it shows negative trends towards established goals, then an action plan is initiated through the Steering Committee for suggestions to improve the Key Business Measureable.

TNT EDM shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices.

TNT EDM shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the

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customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).

If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.

8.5.2 Corrective Action

TNT EDM shall take action to eliminate the **causes** of nonconformities in order to prevent recurrence. Corrective Actions shall be appropriate to the effects of the nonconformities encountered. The following documented procedure has been established and implemented to define the requirements for:

- Reviewing nonconformities (including customer complaints)
 - Nonconforming product is viewed in the form of rework, scrap and customer returns. All customer returns are analyzed using root cause analysis as a part of TNT EDM's disciplined problem solving process.
 - Customer complaints - All customer complaints which include either verbal (phone) or formal complaint format, including returned product, are entered on the Customer Complaint Log ([TNT-F-0017](#)), and are centrally controlled by the Quality System Manager.
 - **Records of Customer Complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside TNT EDM contributed to the customer complaint, relevant information shall be exchanged between the organizations involved.**
 - **If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).**
 - **If National or Regional Regulations require notification of adverse events that meet specified reporting criteria, TNT EDM shall establish documented procedures for such notification to Regulatory authorities.**
- Determining the causes of nonconformities – Root cause analysis is used to determine the causes of nonconformities. Any repetitive types of non-conformities will require implementation of the 7-D problem solving process (if no customer specified manner of problem solving is warranted).
- Evaluating the need for action to ensure that nonconformities do not recur – If any repetitive patterns are identified, the nature of the problem is presented to the Steering Committee to add to the Action Plan ([TNT-F-0010](#)), with responsibilities and timing assigned.
- Determining and implementing actions needed, **including if appropriate, updating documentation (see 4.2)** – Once root cause is determined, assigned responsibility for implementing Corrective Action and timing for implementation is established. In addition, a review of current procedures and work instructions is performed in order to determine the appropriate changes required to the Quality Management System.

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- Records of the results of **investigations and** actions taken (see 4.2.4)– Records are maintained in the database to support closure to all identified product or process nonconformities.
- Reviewing **the effectiveness of the** Corrective Action taken **and its effectiveness** – Part of the follow-up to implementation of Corrective Action taken is the determination that the Corrective Action taken is effective. This is a process of follow-up and/or increased frequency of the Internal Audit process.
- **Flowing down of the Corrective Action requirement to a supplier when it is determined that the supplier is responsible for the nonconformity.**
- **Specific actions where timely and/or effective Corrective Actions are not achieved, and**
- **Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.**

TNT EDM has also established and implemented a work instruction governing the Corrective Action Process. (“Corrective and Preventive Actions” ([TNT-WI-0025](#)))

8.5.3 Preventive Action

TNT EDM shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. The following is the documented procedure established and implemented for:

- Determining potential nonconformities and their causes,
- Evaluating the need for action to prevent occurrence of nonconformities,
- Determining and implementing action needed,
- Records of results of **investigations and of** action taken (see 4.2.4), and
- Reviewing **the effectiveness of the** preventive action taken **and its effectiveness.**

NOTE: Examples of preventive action opportunities include risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.

TNT EDM has also established and implemented a work instruction governing the Preventive action process. (“Corrective and Preventive Actions” ([TNT-WI-0025](#)))