AS9100 Quality Manual

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Section 1: Welcome

TNT-EDM, Inc. has established a Quality Management System (QMS) and manages processes in accordance with AS9100C (Note: Where AS9100 is read, it is to be understood AS9100C). TNT-EDM, Inc. is located at 47689 Anchor Court, Plymouth, MI. 48170.

TNT-EDM, Inc.

TNT-EDM, Inc. is a manufacturer of production and specialty components for the automotive, aerospace, and medical device industries. TNT-EDM processes include but are not limited to Sinker EDM, Wire EDM, High-Speed CNC Milling, CNC Lathe, 5-Axis Machining, Grinding, and Bench Polishing.

TNT-EDM, Inc. has always applied high quality standards to its processes and operations, and continues its dedication in maintaining high levels of quality and integrity in communicating with people inside and outside of its business operation.

We invite you to review our quality system in action. To arrange a visit, contact us at:

TNT-EDM, Inc.
47689 Anchor Court
Plymouth, MI. 48170
(734) 459-1700 – Phone
(734) 459-1745 – Fax
Website: www.tntedm.com
Section 2: TNT-EDM, Inc. Philosophy and Governing Policies

COMPANY PHILOSOPHY

At TNT-EDM, our people are our most important resource. The contribution of each employee to the quality of our products and achieving total customer satisfaction is the basis for our continuing growth and success. We will constantly strive to maintain an atmosphere in which 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, Inc. is dedicated to continuous improvement in all facets of its business to enhance our customers’ and our continued long-term profitable growth.

Section 3: Terms and Definitions

3.1 Scope

TNT-EDM’s quality management system applies to all processes within all functional areas of TNT-EDM’s business operation. The company’s scope is defined in section 1 of this manual.

3.2 Exclusion

Due to the nature of the organization and its product, TNT-EDM is excluded from compliance to requirements of AS9100;

Clause 7.3, Design and Development is excluded from the scope of TNT-EDM’s quality management system because TNT-EDM does not perform design work.

Clause 7.5.1.4, Post-Delivery Support is excluded from the scope of TNT-EDM’s quality management system because TNT-EDM does not provide post-delivery support.

These exclusions do not affect the ability or responsibility of TNT-EDM, Inc. to provide product that meets customer and applicable statutory and regulatory requirements.
3.3 Definitions

Unless otherwise noted, TNT-EDM applies the definition of terms according to ISO 9000 and AS9100.

Capture – To identify and determine

VISTA – VISTA Production Management System

**Section 4: Quality Management System**

4.1 General Requirements

TNT-EDM has established, documented, implemented, and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of AS9100. Furthermore, TNT-EDM's QMS addresses customer and applicable statutory and regulatory management system requirements.

TNT-EDM has;

a. determined the processes needed for the quality management system and their applications throughout the organization, see figure 1
b. determined the sequence and interaction of these processes, see figure 1
c. determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
d. ensured the availability of resources and information necessary to support the operation and monitoring of these processes,
e. monitored, measured, where applicable, and analyzed these processes,
f. implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes, their sequence and interaction (including any outsourced processes) are shown in Figure 1.
FIGURE 1. TNT-EDM QUALITY MANAGEMENT SYSTEM

- Set Objectives
- Set Policy
- Review System
- Communicate
- Allocate Resources

RESOURCE ALLOCATION
- Ensure Competency
- Maintain Infrastructure
- Maintain Work Environment

MANAGEMENT PROCESS
- Set Objectives
- Set Policy
- Review System
- Communicate
- Allocate Resources

PLANNING

VISTA TRAVELLER

NEXT STEP

IN HOUSE

OUTSIDE PROCESS

PRODUCTION STEP

INSPECT

- PASS
- FAIL

MRB

COMPLETE?

YES

PACKAGE AND SHIP

SUBCONTRACT

IMPROVEMENT PROCESSES
- Internal Audits
- Corrective Action
- Preventive Action

SUPPORT PROCESSES
- Calibration
- Training
- Document Control
- Records Maintenance

RFQ

QUOTE

CUSTOMER ORDER

NEXT STEP
4.2 Documentation

4.2.1 Overview of Documentation

TNT-EDM maintains all required documentation to effectively sustain its quality management system. Management is responsible for implementation of procedures and records in their areas as required by the quality management system.

The quality system documentation is comprised of a hierarchy of documents that flow from AS9100 and this quality manual. Procedures support and enhance the primary mandates of TNT-EDM’s company philosophy and quality policy as defined in section 2. Quality objectives may be found in Appendix D of this document.

Hierarchy of Documents
TNT-EDM maintains a secure intranet that allows authorized users to access documents as needed throughout TNT-EDM's organization. Obsolete documents are identified as such and stored separately to prevent unintended use.

Documents and records determined to be necessary for effective planning, operation, and control of processes, unless otherwise directed by the customer requirements are as follows:

- Customer Contract / Purchase Order
- Engineering Data
- VISTA Traveler
- Inspection Records
- Government specifications
- Vendor / Seller Specifications

The extent of the QMS documentation is appropriate for the size of the TNT-EDM organization, its activities, the complexity, and interaction of the quality processes.

4.2.2 Quality Manual and Procedures

The primary purpose of the quality manual and QMS procedures is to describe and document the quality management system in place at TNT-EDM, Inc. and to define all the QMS processes in use within TNT-EDM, Inc. This manual is issued under the authority of the top management.

Copies of the manual are controlled by means as described below. Uncontrolled copies may be distributed as requested and are identified as "Uncontrolled". It is meant to be used by employees as the primary source of official TNT-EDM quality policies. This manual is accessible to customers, regulatory authorities, and third parties that wish to verify TNT-EDM's quality management system. Externally distributed copies will be uncontrolled and not subject to revision unless otherwise agreed.

Additional procedures and work instructions have been developed to further clarify specific instructions for the execution of these procedures. Where subordinate documents are referenced, they are shown in bold italics.

The Management Representative is responsible for control and distribution of this manual and all other controlled documentation within the quality management system. The latest revision of this document is located on the TNT-EDM intranet. Users shall verify the latest revision before use. Contact the Management Representative for questions related to this manual.
Minor corrections (typographical errors and clarification) are not considered a change; therefore, change in revision status is not required.

Documented procedures established for the QMS may be found in Appendix B: Master Procedures List.

Interaction between processes of the QMS may be found in Appendix A: Advanced Processes and Applicable AS9100 Clauses.

### 4.2.3 Control of Documents

Documents are controlled so that the information on them is accessible, legible and suitably maintained. Documents are reviewed and approved prior to release and only the latest revisions are available to users. Previous revisions are segregated and retained electronically in a folder labeled “obsolete”.

The controls for documents are defined in the *TNT-P-0035 Control of Documents*.

### 4.2.4 Control of Records

Records are controlled to provide evidence of conformity to requirements. Records that are subject to control are maintained according to the *TNT-P-0036 Control of Records* and TNT-EDM's Purchase Order Terms and Conditions.

### Section 5: Management Responsibility

#### 5.1 Management Commitment

TNT-EDM’s management is committed to the ongoing maintenance and improvement of the quality management system. To ensure this, management focuses on deploying practical steps that concretely support the quality policy.

- **CUSTOMER FOCUS:** TNT-EDM communicates the importance of meeting customer, regulatory and statutory requirements through employee orientation (see 6.2.2) and by providing documentation of requirements and workmanship criteria (see 7.5.1.1 and 8.2.1). The Contract Review process ensures that customer requirements are captured and reviewed before acceptance (see 7.2).
- **EMPOWERMENT:** All employees are empowered to submit requests for corrective or preventive action to affect change and improve TNT-EDM and its processes and their own experience at TNT-EDM (see 8.5). All employees are empowered to stop production when nonconformities are encountered (see 8.3).

- **INTELLIGENT MANAGEMENT:** TNT-EDM aims to ensure that management makes decisions based on facts, data and evidence. To do this, management has established quality objectives (see 5.4.1). The internal audit process relies on the recording of verifiable data as a means of driving corrective and preventive actions as well as improvement efforts (see 8.2.2, 8.5.2, 8.5.3). By conducting periodic management reviews of the quality system, management ensures the overall effectiveness of the quality system (see 5.6). The **TNT-P-0025 Corrective and Preventive Action Process** procedure ensures that action is taken if planned results are not achieved.

- **WORKPLACE EXCELLENCE:** TNT-EDM ensures the work environment, facilities and atmosphere are satisfactory to employees through management's understanding and review of resource requirements (see 5.6) and through ongoing communication with employees regarding the workplace (see 5.5.3).

### 5.2 Customer Focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing 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 quality policy has been developed and approved by the Management Representative. This policy and relevant procedure is available to all employees. The policy is audited regularly to ensure its distribution and the ongoing overall awareness of it by employees. During management review, the quality policy is reviewed for continual suitability. The quality policy is contained inside the quality manual that is controlled according to the **TNT-P-0035 Control of Documents** procedure. The quality policy may also be issued as a stand-alone document; in this occurrence it is uncontrolled if printed.

### 5.4 Planning
5.4.1 Quality Objectives

Top management has established the quality objectives for the entire organization of TNT-EDM; these objectives apply to all TNT-EDM personnel.

Appendix D defines all of the quality objectives currently in place.

5.4.2 Quality Management System Planning

This quality system was planned. Its documented policies and procedures were reviewed prior to implementation. Management ensures the QMS is maintained when changes to the QMS are planned and implemented. Subsequent major changes that may affect the performance, quality or reliability of the product will be identified, reviewed and approved and the QMS documentation will be updated.

The QMS documentation acts as the overall quality plan for TNT-EDM. As required, specific quality processes may be developed for individual products; these plans include the information given above. In such cases, the appropriate department manager (with support from the Quality Manager) has overall responsibility for the development of quality plans.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The organizational chart on the following page defines the basic management structure of TNT-EDM. In all cases, the appropriate person has been granted both the responsibility and authority for the duties of their position, which are further defined within position specific job descriptions.
5.5.2 Management Representative

The Quality Manager has been assigned the role of Management Representative. As Management Representative, the Quality Manager is responsible for ensuring the proper implementation of the quality system, as well as, for overseeing the maintenance of the system, reporting on its effectiveness during management review, and discussion of matters relating to the quality management system with customers, registrars and other concerned parties.

The management Representative is responsible for facilitation of these policies and procedures. The Management Representative has the responsibility and authority to resolve matters relative to quality in products, processes and service from internal and external sources. Quality may suspend internal and external processes and/or shipments that do not meet requirements until appropriate correction is implemented on an expedited, high priority basis.
The quality Manager reports directly to the Chief Executive Officer and has unrestricted access to top management. Inspectors and auditors report directly to the Quality Manager. In addition, the Management Representative ensures the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal Communication

Top management shall ensure that appropriate communication processes (such as communication boards and company meetings) are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Top management shall review the QMS, at yearly intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and objectives. Records (management review meeting minutes) are maintained using TNT-F-0061 BOS Meeting Agenda and Minutes.

5.6.2 Review Input

Items that will appear on the agenda will include:

a. Action items assigned in last review meeting – follow up  
b. Customer feedback and complaints  
c. Internal or external audit results  
d. Continual improvement projects or recommendations  
e. Corrective and preventive actions  
f. Resource needs  
g. Changes that could affect the quality system  
h. Product conformity (scrap, rework)  
i. Changes in quality policy or objectives  
j. Customer satisfaction progress  
k. Company level data (BOS Metrics)

5.6.3 Review Output

The following items will appear in the meeting minutes:
a. Improvement of the effectiveness of the quality management system and its processes
b. Improvement of the product related to customer requirements, and
c. Resource needs

Section 6: Resource Management

During management review, TNT-EDM's management determines and provides the resources needed to implement and maintain the quality management system and continually improve its effectiveness. Resources needed to enhance customer satisfaction by meeting customer requirements are also determined and provided.

6.3 Human Resources

6.2.1 General

All TNT-EDM employees shall be competent on the basis of appropriate education, training, skills, and experience.

6.2.2 Competence, Training and Awareness

For full-time, part-time, and temporary employees, TNT-EDM

a. Has determined the necessary competence for personnel performing work affecting conformity to product requirements,
b. Where applicable, provides training or takes other actions to achieve the necessary competence,
c. Evaluates the effectiveness of this training,
d. Ensures personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and,
e. Maintains appropriate records of education, training, skills and experience (see 4.2.4).

TNT-EDM’s management regularly reviews the knowledge, capabilities and skill needs of the organization against those available. In any instance where there is a gap between needs and capability, the functional manager will take the necessary steps to acquire needed knowledge, capabilities and/or skills.
This may include training and skills development for existing employees, or the use of consultants or other outside expertise.

Necessary competencies are spelled out within job descriptions which are maintained for all positions. New hires are selected based upon whether they meet the needs described in these job descriptions. New and existing personnel are provided with orientation and any necessary training in order to meet the requirements of their given position.

6.3 Infrastructure

TNT-EDM has determined and provides and maintains the basic infrastructure needed to achieve conformity to product requirements. Infrastructure requirements are regularly reviewed during management review and include the review of:

- Building(s), workspace, and associated utilities,
- Process equipment (both hardware and software), and
- Supporting services (such as transportation, communication or information systems)

Specifically, TNT-EDM has established a production facility with the necessary environmental controls for factors including temperature, humidity, lighting, and cleanliness. Facilities undergo routine preventive maintenance by skilled maintenance personnel.

TNT-EDM’s internal server is equipped with a battery backup system preventing loss of power and data in the event of a power outage. In the event of a sustained power outage, loss of data is prevented through daily backup on an analog tape, which is stored in a fireproof safe on site or critical data is backed up daily through an off-site third party data storage vault.

6.4 Work Environment

TNT-EDM has determined and manages the work environment, including noise, temperature, humidity, and lighting, needed to achieve conformity to product requirements. The work environment is periodically reviewed during internal audits and work environment-related resource requirements are regularly reviewed during management review.

Section 7: Product Realization
7.1 Planning of Product Realization

In planning the processes for product realization, management has ensured that the processes are consistent with the requirements of the other processes within the quality system.

Planning includes the following:
   A. Quality objectives and requirements for the product;
   B. The need to establish processes and documents, and to provide resources specific to the product;
   C. Required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance;
   D. Records needed to provide evidence that the realization processes and resulting product meet requirements;
   E. Configuration management appropriate to the product;
   F. Resources to support the use and maintenance of the product.

The output of the planning is the VISTA traveler, related drawings, inspection packages, operator check sheets, and specifications that show dimensions, characteristics, tolerances, and any key characteristic identified by TNT-EDM or the customer. Likewise, these instructions define any processes, documents or resource requirements specific to the product. Inspection, testing and other monitoring steps will also be defined in the VISTA traveler.

7.1.1 Project Management

Project management is a process designed to ensure customer requirements are met. During project management, managers plan and manage product realization in a structured and controlled manner. Resource needs and schedule constraints are considered and adjusted as needed. Appropriate actions are taken to mitigate risks as they are determined. These processes are further defined in sections 7.1.2, 7.1.3, 7.2, and 7.5.

7.1.2 Risk Management

Risk management is essential in meeting customer requirements. Managers, or their delegates, communicate with customers, obtaining information that may not be stated in contracts of purchase orders. The information obtained is used in risk management.

Management is responsible for risk management and taking action to mitigate risks. Factors such as labor, equipment, material, scheduling, and outside processing are identified throughout contract review,
purchasing, planning, production, and inspection processes. Documents are created or revised, and meetings are held as needed to address and communicate risks that have been identified. Internal preventive and corrective action is closely integrated into risk management. As risks are identified these actions may be used to mitigate/resolve risks (see 8.5.2 and 8.5.3).

Prior to acceptance of contract or purchase order, relevant risk criteria are assessed to identify risk and determine feasibility. Criteria may include but are not limited to:

- Engineering data (e.g., drawings, models, specifications, etc.) are made available,
- Customer supplied quality requirements and/or vendor manual,
- Configuration plan,
- Quantity and delivery schedule,
- Requirements for customer approved suppliers,
- Lead time and cost for raw material and/or hardware items,
- Lead time and cost for outside processing (e.g., heat treat, plating, etc.),
- Cost of any non-recurring charges, if any,
- Labor hours and skill,
- Equipment (e.g., tooling, fixtures, and resources),
- Inspection and test plans,
- Any special requirements and expectations not stated in request.

If any of the above criteria cannot be resolved, or causes unease to trained personnel, then the order is considered “high risk”.

On “high risk” orders:

- Top management investigates, confirms, and documents any risk associated with the order.
- Results of this assessment are logged on *TNT-F-0058 Internal Feasibility Review Form*.
- If the decision to accept risk is made, the appropriate personnel will be notified and the mitigation process will continue.

### 7.1.3 Configuration Management

Configuration management includes planning, identification, change control, status accounting, and auditing. Configuration audits are conducted during internal audits. Contracts for new products and changes to existing products are processed in accordance with section 7.2.

Part configuration is provided in the customer’s engineering specifications. Configuration is identified on the VISTA traveler and subsequent shipping documents. When the product requirements change, the
manufacturing plan is revised and appropriate personnel are informed of the change. This process is further defined in section 7.5.

Configuration is controlled through verification during manufacturing. Evidence of verification is recorded on VISTA travelers and inspection records as defined in section 8.2.4.

7.1.4 Control of Work Transfers

When planning to temporarily transfer work TNT-EDM defines the process to control and validate the quality of work per the customer requirements and/or the vendor check sheet.

A. The outsourced service provider must be an approved, evaluated supplier according to the requirements of section 7.4,
B. The supplier is required to notify TNT-EDM of any process changes, any nonconformity, or other issues,
C. The supplier will be subject to the corrective action system, as defined in section 8.5.2.
D. Work must be conducted on the article(s) according to any specification listed on the purchase order.

This process is controlled through purchasing and resultant receiving documentation. Product and quality requirements are flowed down in purchase orders as described in section 7.4.2.

7.2 Customer Related Processes

7.2.1 Determination of Requirements

TNT-EDM captures all contractual and special requirements, monitoring and measurement requirements, applicable statutory or regulatory requirements, and/or any necessary, unstated requirements as part of the contract review process.

7.2.2 Review of Requirements

Once contractual and special requirements are captured, and risks determined, they are reviewed against previous contract or order requirements and differences are resolved. Relevant documents are changed as
requirements change, as defined in section 7.1.3. TNT-EDM determines their capability to meet customer requirements before acceptance of the order.

Order entry into VISTA is a record of review. Records of actions arising from the review shall become part of the work package.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by requesting customer approval of quote or by feedback through electronic communications or phone ("or phone" is for non-aerospace parts only).

Where product requirements are changed after work has begun, TNT-EDM shall ensure that relevant documents are amended and that relevant personnel are made aware of the changes.

7.2.3 Customer Communication

TNT-EDM determines and implements effective arrangements for communicating with customers in relation to:

   a. Product information,
   b. Inquiries, contracts or order handling including amendments
   c. Customer feedback, including customer complaints.

7.3 Design and Development

TNT-EDM takes exclusion to design and development from the scope of its QMS per paragraph 3.2.

7.4 Purchasing

7.4.1 Purchasing Process

TNT-EDM ensures purchased products or services conform to specified purchase requirements as defined in the purchase order and referenced documents. The controls applied to the supplier and to the purchased product or service vary, dependant on the effect of the purchased product or service on TNT product.

Purchasing is a process within the TNT-EDM QMS. TNT-EDM accepts responsibility for the conformity of products that are purchased from suppliers including product from sources defined by the customer. TNT-
EDM does not use customer verification as evidence of effective control of quality by the supplier. However, TNT-EDM does accept responsibility for the conformity of Products or Material (e.g., castings) provided by the customer.

Supplier selection and Evaluation is defined in *TNT-P-0028 Purchasing Process Supplier Evaluation.*

The purchasing process ensures TNT-EDM manages risk when selecting and using suppliers and only purchases materials and services from suppliers that have undergone evaluation and approval.

### 7.4.2 Purchasing Information

Purchase orders are used to transmit TNT-EDM’s requirements to suppliers.

Purchase orders include statements in our “terms & conditions” section concerning the following items, when and where we require these items:

- **a.** Requirements for approval of product, procedures, processes and equipment,
- **b.** Requirements for qualification of personnel,
- **c.** Quality management system requirements,
- **d.** Drawing and/or specifications (or other technical data) and applicable revision,
- **e.** Requirements for design, test, examination, inspection, and related instructions for acceptance,
- **f.** Requirements for test specimens, design approval, inspection/verification, investigation or auditing,
- **g.** Requirements for supplier notification to TNT-EDM of nonconforming product, requirements for the supplier to notify TNT-EDM of changes in product and/or process definition and, where required, obtain organizational approval for nonconforming product disposition, requirements for the supplier to flow down applicable requirements,
- **h.** Records retention requirements,
- **i.** Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and

When any of these items are required by TNT-EDM, the required items is clearly stated on the first page of the Purchase Order. TNT-EDM ensures adequacy of specified purchase requirements before communicating them to the supplier.

### 7.4.3 Verification of Purchased Product

TNT-EDM has established receiving inspection and/or other activities necessary to ensure purchased product meets specified purchase requirements.
Receiving department uses certificates of conformity, test reports, and/or visual and dimensional inspection to verify product conformity.

Without exception, purchased product or material shall not be used or processed until it has been properly received.

TNT-EDM does not delegate inspection to suppliers.

Where specified by contract, TNT-EDM’s customer shall be afforded the right to verify at the suppliers’ premises or at TNT-EDM’s premises that subcontracted product conforms to specified requirements. Verification by the customer shall not be used by TNT-EDM as evidence of effective control of conformity by the supplier and shall not absolve TNT-EDM of the responsibility to supply acceptable product, nor shall it preclude subsequent rejection by the customer.

7.5 Production

7.5.1 Control of Production

TNT-EDM plans and carries out production under controlled conditions. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product,
- The availability of work instructions as necessary,
- The use of suitable equipment
- The availability and use of monitoring and measuring equipment,
- The implementation of monitoring and measuring,
- The implementation of product release and delivery,
- Accountability for all products during production (e.g., parts quantities, split orders, nonconforming product),
- Evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
- Provision for the prevention, detection, and removal of foreign objects,
- Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect conformity to product requirements, and
Planning Considers, as applicable,

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

7.5.1.1 Production Process Verification

TNT-EDM provides for the inspection, verification and documentation of representative item from the first production run of a new part or assembly, or following any subsequent change that invalidates the previous first article inspection result.

7.5.1.2 Control of Production Process Changes

CEO, Program Manager, Production Manager, and Quality Manager have the authority to approve changes to production processes.

To ensure product conformity, TNT-EDM shall validate production processes, equipment, tools, setup and software programs prior to production or after changes have been made through first piece inspection at each operation.

Software programs, equipment, and process changes shall be documented on the VISTA traveler. Permanent revisions to the VISTA Traveler shall be made in VISTA and the specific changes documented in the comments section, so revisions can be tracked. Temporary revisions may be hand written on the VISTA Traveler and must be initialed and dated by someone with approval authority.

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 will be validated prior to release to production and will be maintained.
Production equipment shall be maintained in accordance with established preventive maintenance plans (TNT-WI-0009 Preventive Maintenance Process), and shall be logged.

Holding fixtures (vises, jaws, etc.), when not in use shall be stored indoors. They shall be lubricated and inspected as necessary before use.

7.5.1.4 Post-Delivery Support

As of this revision, TNT-EDM has no contractual requirements relating to post-delivery support. Therefore, TNT-EDM takes exclusion from 7.5.1.4; this exclusion does not affect the ability or responsibility of TNT-EDM to provide product that meets customer and applicable regulatory requirements.

7.5.2 Validation of Processes for Production (Special Processes)

Validation demonstrates the ability of these processes to achieve planned results.

TNT-EDM shall specify arrangements for these processes including, as applicable

a. Defined criteria for review and approval of the processes,
b. Approval of equipment and qualification of personnel,
c. Use of specific methods and procedures,
d. Requirements for records (see 4.2.4), and
e. Revalidation

7.5.3 Identification and Traceability

Product is identified by suitable means throughout product realization.

TNT-EDM shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration. Product status with respect to monitoring and measuring requirements is identified; nonconforming parts are identified (and segregated) in accordance with TNT-P-0029 Control of Nonconforming Product.

Where traceability is a requirement, TNT-EDM controls and records the unique identification of the product according to the level of traceability required by contract, regulatory, or other established requirements.
TNT-EDM system provides for:

a. Identification to be maintained throughout the product life;
b. All the products manufactured from the same batch of raw material or from the same manufactured batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
c. For an assembly, the identity of its components and those of the next higher assembly to be traced;
d. For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

7.5.4 Customer Property

TNT-EDM exercises care with customer property while it is in TNT-EDM’s control or use. TNT-EDM shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, TNT-EDM will report it to the customer and records maintained in accordance with TNT-WI-0024 Processing Customer Property.

Customer property may include intellectual property and personal data.

7.5.5 Preservation of Product

TNT-EDM preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of the product.

Preservation of product also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements provisions for:

a. Cleaning,
b. Prevention, detection, and removal of foreign objects,
c. Special handling for sensitive products,
d. Marking and labeling including safety warnings,
e. Shelf life control and stock rotation,
f. Special handling for hazardous materials.

7.6 Control of Monitoring and Measuring Equipment

TNT-EDM determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product in accordance with TNT-P-0040 Control of Monitoring and Measuring Equipment.

Section 8: Measurement, Analysis, & Improvement

8.1 General

TNT-EDM plans and implements the monitoring, measuring, analysis and improvement processes needed:

a. To demonstrate conformity to product requirements,
b. To ensure conformity of the quality management system, and
c. To continually improve the effectiveness of the quality management system.

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

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 monitors information relating to customer perception as to whether the organization has met customer requirements. The method for obtaining and using this information is determined.

TNT-EDM collects feedback from customers using one or more of the following methods to monitor and measure customer satisfaction:

a. Corrective action requests
b. Customer complaints
TNT-EDM has developed and implemented a plan for customer satisfaction improvement that addresses deficiencies identified by the above evaluations, and assesses the effectiveness of the results. See 5.6 Management Review.

8.2.2 Internal Audit

TNT-EDM conducts internal audits at planned intervals to determine whether the quality management system:

a. Conforms to the planned arrangements, to the requirements of AS9100 and to the quality management system requirements established by TNT-EDM, and
b. Is effectively implemented and maintained.

Internal audits are performed in accordance with TNT-P-0037 Internal Audits.

TNT-EDM maintains the authority to outsource the internal auditing process to a certified third party auditor. See appendix C Internal Auditing.

8.2.3 Monitoring and Measuring of Processes

TNT-EDM shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate.

In the event of process nonconformity, TNT-EDM

a. Takes appropriate action to correct the nonconforming process,
b. Evaluates whether the process nonconformity has resulted in product nonconformity,
c. Determines if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
d. Identifies and controls any nonconforming product.

8.2.4 Monitoring and Measurement of Product
TNT-EDM monitors and measures the characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria will be maintained.

Measurement requirements will include:

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

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

When TNT-EDM uses sampling inspection as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate use.

Product is not to be released until it has been inspected or otherwise verified as conforming to specified requirements.

Records indicate the person(s) authorizing release of product for delivery to customer.

Where required to demonstrate product qualification TNT-EDM ensures that records provide evidence that the product meets the defined requirements.

Product release and delivery will not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

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

8.3 Control of Nonconforming Product

TNT-EDM ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The responsibilities, authorities, and controls for controlling nonconforming product are defined in TNT-P-0029 Control of Nonconforming Product.
8.4 Analysis of Data

TNT-EDM determines, collects and analyzes 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 includes data generated as a result of monitoring and from other relevant sources.

The analysis of data provides information relating to:

a. Customer satisfaction (see 8.2.1),
b. Conformity to product requirements (see 8.2.4)
c. Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and
d. Suppliers (see 7.4).

8.5 Improvement

8.5.1 Continual Improvement

TNT-EDM continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

TNT-EDM monitors the implementation of improvement activities and evaluates the effectiveness of the results.

8.5.2 Corrective Action

TNT-EDM takes action to eliminate the cause(s) of nonconformities in order to prevent recurrence in accordance with **TNT-P-0025 Corrective and Preventive Action Process**. Corrective actions are appropriate to the effects of the nonconformities encountered.

8.5.3 Preventive Action

TNT-EDM determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence in accordance with **TNT-P-0025 Corrective and Preventive Action Process**. Preventive actions are appropriate to the effects of the potential problems.
## Appendix A: Advanced Processes and Applicable AS9100 Clauses

<table>
<thead>
<tr>
<th>Process</th>
<th>Applicable AS9100 Clause</th>
</tr>
</thead>
</table>
| Corrective & Preventive Action | 8.5.2 Corrective Action  
8.5.3 Preventive Action                      |
| Design and Development      | Excluded                                                                                |
| Internal Auditing           | 8.2.2 Internal Audits                                                                   |
| Management                  | 4.1 QMS General Requirements  
4.2 Documentation Requirements  
5.1 Management Commitment  
5.2 Customer Focus  
5.3 Quality Policy  
5.4 Planning  
5.5.1 Responsibility & Authority  
5.5.2 Management Representative  
5.5.3 Internal Communication  
5.6 Management Review  
6.1 Provision of Resources  
6.2 Human Resources  
6.3 Infrastructure  
6.4 Work Environment  
7.1.2 Risk Management  
7.1.3 Configuration Management  
7.2.3 Customer Satisfaction  
7.5.1 Control of Production Provision  
7.6 Control of Monitoring & Measuring Equipment  
8.1 Measurement Analysis & Improvement: General  
8.2.1 Customer Satisfaction  
8.2.3 Monitoring and Measurement of Processes  
8.4 Analysis of Data  
8.5.1 Continual Improvement |
| Manufacturing               | 7.1 Planning of Product Realization  
7.5.1.1 Production Documentation  
7.5.1.2 Control of Production Process Changes  
7.5.1.3 Control of Production Equipment  
7.5.1.4 Post Delivery Support  
7.5.3 Identification & Traceability  
7.5.4 Customer Property  
7.5.5 Preservation  
8.2.4 Monitoring and Measuring of Product  
8.3 Control of Nonconforming Product |
| Contract Review             | 7.2.1 Purchasing Process  
7.2.2 Review of Requirements |
| Purchasing                  | 7.4.1 Purchasing Process  
7.4.2 Purchasing Information |
| Receiving                   | 7.4.3 Verification of Purchased Product  
7.5.3 Identification & Traceability  
7.5.4 Customer Property  
7.5.5 Preservation  
8.2.4 Monitoring & Measurement of Product  
8.3 Control of Nonconforming Product |
| Shipping                    | 7.5.3 Identification & Traceability  
7.5.5 Preservation  
8.3 Control of Nonconforming Product |
Appendix B:  Master Procedure List

<table>
<thead>
<tr>
<th>TNT Procedure No.</th>
<th>Procedure</th>
<th>AS9100 Reference</th>
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<tr>
<td>TNT-P-0001</td>
<td>File Backup Procedure</td>
<td>4.2.3</td>
</tr>
<tr>
<td>TNT-P-0025</td>
<td>Corrective / Preventive Action</td>
<td>8.5.2, 8.5.3</td>
</tr>
<tr>
<td>TNT-P-0028</td>
<td>Purchasing / Supplier Development</td>
<td>7.4.1</td>
</tr>
<tr>
<td>TNT-P-0029</td>
<td>Control of Nonconforming Product</td>
<td>8.3</td>
</tr>
<tr>
<td>TNT-P-0035</td>
<td>Control of Documents</td>
<td>All</td>
</tr>
<tr>
<td>TNT-P-0036</td>
<td>Control of Records</td>
<td>4.2.3</td>
</tr>
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<td>TNT-P-0037</td>
<td>Internal Audit</td>
<td>8.2.2</td>
</tr>
<tr>
<td>TNT-P-0038</td>
<td>Risk Management</td>
<td>7.1.2</td>
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<td>TNT-P-0039</td>
<td>Control of Manufactured Product</td>
<td>7.3</td>
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<td>TNT-P-0040</td>
<td>Control of Monitoring and Measuring Equipment</td>
<td>7.6</td>
</tr>
</tbody>
</table>
Appendix C: Outsourced Processes

The following processes are outsourced and controlled as indicated:

- **Acceptance Testing:** Only approved laboratories are used. All lab results must be accompanied by a certificate or test result that is viewed by the Quality Manager. Where applicable, tests must be conducted according to specifications referenced on the purchase order.

- **Calibration:** Only approved calibration labs are used according to *TNT-P-0040 Control of Monitoring and Measurement Equipment*. Certificates must provide evidence of standard traceability to NIST and must meet all requirements of section 7.6 of this quality manual.

- **Internal Auditing:** Contract internal auditors shall provide evidence of having attended, at a minimum, a 16 hour ASQ, RABQSA, or IRCA certification or equivalent course; furthermore, the service provider is subject to all other vendor evaluation and monitoring and must follow internal auditing procedures as required.

- **Plating / Coating**
- **Sub-contract Machining**
- **Heat Treating**
- **Welding**
## Appendix D: Quality Objectives

<table>
<thead>
<tr>
<th>Objective</th>
<th>Objective Target</th>
<th>Measurement Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase On-time Delivery</td>
<td>≥ 98 %</td>
<td>Percent of deliveries made within agreed window</td>
</tr>
<tr>
<td>Reduce C.O.P.Q</td>
<td>&lt; $2,500</td>
<td>Combined cost for scrap and rework per month</td>
</tr>
<tr>
<td>(Cost of Poor Quality)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase Customer Satisfaction</td>
<td>100 %</td>
<td>Customer Score Cards</td>
</tr>
<tr>
<td>Purchasing</td>
<td>100 %</td>
<td>Supplier on time delivery</td>
</tr>
</tbody>
</table>
Appendix E: Production Flow Chart

1. RFQ
2. CUSTOMER ORDER
3. QUOTE
4. PLANNING
5. VISTA TRAVELLER
6. NEXT STEP

SUBCONTRACT
**REVISION LOG**

<table>
<thead>
<tr>
<th>Revision</th>
<th>Date</th>
<th>Changes</th>
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<tr>
<td>3</td>
<td>1.11.05</td>
<td>Unknown Change</td>
</tr>
<tr>
<td>4</td>
<td>1.25.07</td>
<td>Revised section 7.4.1 (Purchasing Process) by the addition of annual validation of approved supplier list status</td>
</tr>
<tr>
<td>5</td>
<td>6.25.07</td>
<td>Updated entire manual to include the requirements for ISO-13485:2003 (Medical Devices QMS). All changes added appear in Blue Font</td>
</tr>
<tr>
<td>6</td>
<td>7.25.07</td>
<td>Updated entire manual to include the requirements for USNRC-10 CFR Part 21 “Nuclear Safety Related (including ASME III) Material cutting and machining processes</td>
</tr>
<tr>
<td>7</td>
<td>9.7.07</td>
<td>Updated entire manual to include the requirements for AS9100B/ISO-9001:2000 by Highlighting Yellow the additional Aerospace Requirements not already addressed within the QMS for ISO-9001:2000</td>
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<tr>
<td>8</td>
<td>11.19.07</td>
<td>Revised section 7.5.1.2 for Quality Manager to approve changes made by authorizing manufacturing personnel to verbally notify the quality manager or project manager.</td>
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<td>10</td>
<td>7.15.2008</td>
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<tr>
<td>11</td>
<td>1.8.09</td>
<td>Unknown Change</td>
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See TNT-P-0029

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**AS9100 Quality Manual**

**Revision 15**

TNT-EDM, INC.
47689 Anchor Court
Plymouth, MI 48170
<p>| | | |</p>
<table>
<thead>
<tr>
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<tr>
<td>13</td>
<td>9.28.09</td>
<td>AS9100C/ISO-9001:2008 by Highlighting Blue the additional Aerospace requirements not already addresses within the QMS for ISO-9001:2008</td>
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<tr>
<td>14</td>
<td>11.11.11</td>
<td>Complete re-write of entire manual to address all AS9100C / ISO-9001:2008 requirements. Management Review of previous revision warranted a revision for ease of use and comprehension and to better represent our current state of business.</td>
</tr>
<tr>
<td>15</td>
<td>5-23-12</td>
<td>Added purchasing to appendix D quality objectives. Modified page 22 concerning P.O. terms &amp; Conditions</td>
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