QUALITY ASSURANCE MANUAL QUALITY POLICY MANUAL *WEBSITE DOCUMENT				DP07-0101 Page 1 of 27
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A	4591	Initial Release to AS9100 Revision B	SN	03/03/07
B	4644	General formatting changes, no content change	CES	05/02/07
C	4825	Updated to include EN13980 requirements, added reference section, added section 5.5.4 and 5.5.5	SN	09/11/07
D	4841	Added more references to EN13980 and added another responsibility to section 5.5	SN	09/27/07
E	5241	Revised the Quality Manual to change references	SN	05-14-08
F	7098	Revised based on NQA AS9100 Audit, see ECR	CE	09-20-10
G	7129	Revised Appendix: was: Organization Chart for Dytran Instruments, Inc., Is: Functional Org. Chart for Dytran Instruments, Inc.	SN	10-27-10
H	8011	Clarification of section 8.2.4.1 Inspection Documentation	CE	10/27/11
J	10237	Clarification of Dytran SECTION 2 SCOPE AND APPLICATION	EP	08/01/13
K	12166	Changed all reference to EN13980 over to ISO/IEC 80079-34 and added “See DP07-0103” for section 3, Quality Policy.	BA	08/17/15
L	12463	Updated section 5.5.5 with quarterly review of ATEX standards. Update section 5.6.1 to include time interval for review of products intended for use in explosive atmospheres	EP	02/03/16
M	12524	Updated section 5.5.5 with quarterly review of ATEX standards. Update section 5.6.1 to include time interval for review of products intended for use in explosive atmospheres	EP	02/24/16
N	13805	Complete revision to meet the AS9100 Revision D requirements.	MK	10/09/17
P	14348	Added “ISO/IEC 80079-34:2011” to the introduction on page 6 and Section 2. Added “Ensuring that the QMS conforms to the requirements of ISO/IEC 80079-34 standard” to Section 5.3	MK	7/12/2018

REVISION	ECN	DESCRIPTION OF CHANGES	CHANGE BY	DATE
R	16044	Update Introduction section 3 & Section 2 with ISO/IEC 80079-34, was: 80079-34:**2011**	BA	01/05/21
T	16765	Add watermark: "Website Document" Add to footer: "Marketing must be notified of any changes"	BA	06/02/22
U	16775	Update Core Process Diagram 1 – Order review & Planning	DM	06/08/22
V	16781	Updated Design Engineering, Core Process diagram 2 – removed PVR cycle times. Updated Production, Core Process diagram 4: removed: DPD (digital products development).	BA	06/21/22
W	17229	Updated Core Process Diagram 1	DM	07/24/23
Y	17412	Updated Core Process Diagram 1 – Order Review & Planning Updated Core Process Diagram 3 – Purchasing Updated Core Process Diagram 4 – Production Section 5: Leadership, 5.1.1 General	JN	03/25/24

SECTION 0

Introduction

Dytran Instruments developed and implemented a Quality Management System (QMS) to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its context, Dytran Instruments determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the Quality Management System.

The Quality Management System of Dytran Instruments meets the requirements of the international standards ISO 9001:2015, AS9100:2016, & ISO/IEC 80079-34. The system addresses the design, development, and production of the company's products. It incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

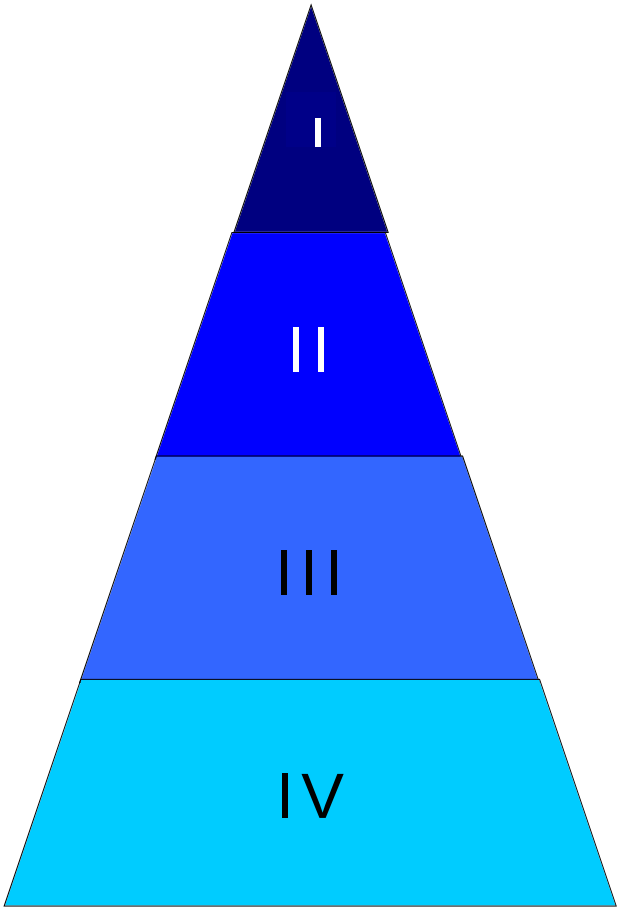
The manual is divided into sections that correlate to the Quality Management System sections of AS9100. The manual describes the Quality Management System, delineates authorities, inter-relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained to ensure customer satisfaction, continual improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continual improvement.

It is the responsibility of the Quality Manager of Dytran Instruments to ensure that this manual is maintained as a current reflection of the Dytran Instruments Quality Management System.

Document Hierarchy



Level I

Quality Assurance Manual

Level II

Documented Procedures
(DPxx-xxxx)
(Reference department Index's)

Level III

Work Instructions (DPxx-xxx, DPM-XXX, etc.)
(Reference department Index's)

Level IV

Forms & Records

NOTE:

Level 1 is our Quality Manual which defines our approach and responsibility.

Level 2 is our procedures which define Who will do What and When to conform to requirements.

Level 3 is our instructions which answer How you will do your processes and procedures. These are more step-by-step instructions.

Level 4 is our prompts for recording information such as forms, labels, test reports etc. Once completed, they become quality records.

Core Process Diagram 1

What: What are the resources needed? ***Equipment:*** Facility, Computer, & Equipment ***Software & Other Resources:*** MS Office & D3 MRP System Visual compliance check CRM system Customer Portals	**Who:** Who applies the resources? ***Process Owner(s):*** Sales Manager & Production Manager ***Process Personnel:*** Sales Engineers, Sales Administrators and Planning	***Special Process Specific Training:*** D3 MRP Training CRM training Visual Compliance training Export Control training Applicable Procedures & Work Instructions listed in "How" section
Inputs: Customer PO, customer drawing, AVL, customer purchase order provisions, Special Requirements, Critical Items, Customer flow down requirements, Special processes requirements, Identification of Approved processors, Risk assessment, product, customer specified sources, delivery, cost. Inspection methods, sampling plan requirements ***Input is from:*** Marketing Sales Customer Order Order History CRM system	Order Review & Planning **Key AS9100 Section(s):** **8.1 & 8.2**	**Outputs:** Price Quote, Confirm sales order to customer, PO to order entry. Risk mitigation plan. Production Planned. In-Process inspection reports. Material certifications and test reports. Special process certifications. Product certifications and test report (if required). FAIR report per AS9102. Special requirements flow down, Traveler with product process identification and transfer control parameters. ***Output is to:*** Sales, Customer, Purchasing, Production, Engineering, & Finance
How: How is this process controlled? ***Procedures:*** DP05-0210 Job Traveler Process DP07-0303 Traveler Release Process DP07-0701 Customer Related Processes DP07-0710 Program Management Process DP07-0711 Risk Management Process DP07-0325 Contract Review Process DP07-0801 Customer Satisfaction Process Order Entry Process (in-process of formalizing) ***Work Instructions/Flow Charts:*** (See related Procedures)	***Forms-Logs-Guides:*** *(& Records)* (SEE RELATED PROCEDURES FOR DETAILED LISTING OF FORMS)	**Measure:** *process effectiveness.* ***Measurement and Metric Selection:*** Order Entry TAT Order Entry Accuracy ***Method for Collection of Data:*** D3 MRP System Excel

Core Process Diagram 2

What: What are the resources needed? ***Materials:*** **Customer communication, Sales communication, internal or external drawings, and internal and/or external specifications.** ***Equipment:*** **Computer, printer** ***Software & Other Resources:*** **MS Office, SolidWorks, SolidWorks Simulation, & D3 MRP System**	**Who:** Who applies the resources? ***Process Owner(s):*** **Engineering Manager** ***Process Personnel:*** **Design Eng., Project Eng., Mfg. Engineer, Quality Engineer, Methods Planner and other personnel as required for design review and planning process**	***Special Process Specific Training:*** **D3 MRP Training** **FOD Training** **ESD Training** **Applicable Procedures & Work Instructions listed in "How" section** **(SEE JOB DESCRIPTIONS FOR LISTED PERSONNEL)**
Inputs: **Drawings- Internal & External, Specs-Internal & External, RFQ, Statutory, Regulatory, & Special Requirements, Test Lab, and Prototype Department** ***Input is from:*** **Contract Review, SCD, SOW, & MPRs**	Design Engineering **Key AS9100 Section(s):** **8.1 & 8.3**	**Output:** **Price Quote, Specifications, Dytran Manufacturing procedures (DMPs), Router/Traveler, Drawings (standard, manufacturing, data check sheets, as applicable), risk mitigation plan if appropriate. Also, a signed engineering change notice (ECN) form.** ***Output goes to:*** **Purchasing, Production, Contract Review, Sales, Marketing, & Customers**
How: How is this process controlled? ***Procedures:*** **DP05-0101 Numbering System** **DP05-0205 Document Control Process** **DP05-0206 New Product Release (NPR) Flow** **DP05-0209 Design Process** **DP05-0210 Job Traveler Process** **DP07-0401 Control of Documents** **DP07-0402 Control of Records** **DP07-0403 Configuration Management** ***Work Instructions/Flow Charts:*** **(See related Procedures)**	***Forms-Logs-Guides: (& Records)*** **(SEE RELATED PROCEDURES FOR DETAILED LISTING OF FORMS)**	**Measure:** *Process effectiveness.* ***Measurement and Metric Selection:*** **ECR Cycle Time** **NPR Cycle Time** ***Method for Collection & Use of Data:*** **ECR, NPR**

Core Process Diagram 3

What: What are the resources needed? ***Materials:*** Office Supplies ***Equipment:*** Computer ***Software & Other Resources:*** MS Office & D3 MRP System	**Who:** Who applies the resources? ***Process Owner(s):*** Purchasing Manager ***Personnel:*** Buyers	***Special Process Specific Training:*** D3 MRP Training Applicable Procedures & Work Instructions listed in "How" section
Inputs: Customer purchase order, Dytran Instruments AVL, customer drawing, Customer Controlled Sources, Dytran Instruments quality assurance and purchase order provisions. ***Input is from:*** Contract Review Planning	Purchasing **Key AS9100 Section(s):** **8.4**	**Outputs:** PO to supplier and associated documentation Quality Clauses, Terms & Conditions Customer Controlled Sources ***Output is to:*** Suppliers Receiving Production Pick & Pack
How: How is this process controlled? ***Procedures:*** DP07-0203 Procurement Quality Requirements DP07-0703 Vendor Selection DP07-0704 Purchasing Process DP07-0709 Control of Work Transfer DP07-0808 Control of Counterfeit Parts/Materials ***Work Instructions/Flow Charts:*** (See related Procedures)	***Forms-Logs-Guides:*** *(& Records)* (SEE RELATED PROCEDURES FOR DETAILED LISTING OF FORMS)	**Measure:** *process effectiveness.* ***Measurement and Metric Selection:*** Supplier Quality (Defects): Defects identified at Dytran Receiving Inspection. Supplier On Time Delivery (OTD): Delivery to the promise date. ***Method for Collection & Use of Data:*** Vendor OTD is tracked through the D3 MRP system.

Core Process Diagram 4

What: What are the resources needed? ***Materials:*** Raw materials, customer supplied property ***Equipment:*** Various Outsourced Production, Scanner, Printer, Computer, Inspection & Test Equipment ***Software & Other Resources:*** MS Office, D3 MRP System, Approved Outsourced Manufacturer	**Who:** Who applies the resources? ***Process Owner(s):*** Business Unit Managers ***Personnel:*** Production Personnel Stockroom Personnel	***Special Process Specific Training:*** FOD Training ESD Training Applicable Procedures & Work Instructions listed in "How" section
Inputs: Customer PO, customer/Dytran drawing, Dytran Instruments PO, purchase order and quality assurance provisions, traveler, completed product in inventory, Calibration records ***Input is from:*** Contract Review & Planning Purchasing	Production **Key AS9100 Section(s):** **8.5, 8.6, 8.7**	**Outputs:** Finished parts, material and process certs, FAI, completed traveler, CofC's, Packaged and labeled finished product, completed Pick List, Shipping Document, Maintenance and calibration schedules ***Output is to:*** Shipping Customer Sales
How: How is this process controlled? ***Procedures:*** DP07-0303 Traveler Release Process DP07-0304 Traveler – Work Order Split Process DP07-0308 Foreign Object Debris (FOD) Management DP07-0309 Preventative Maintenance DP07-0705 Preservation of Product DP07-0706 Control of Monitoring and Measurement Equipment DP07-0805 Control of Nonconforming Products DP07-0806 Monitoring/Measurement of Products-Processes DP07-0809 Control of Production & Service Provision ***Work Instructions/Flow Charts:*** (See related Procedures or DMP-000 INDEX)	***Forms-Logs-Guides: (& Records)*** (SEE RELATED PROCEDURES FOR DETAILED LISTING OF FORMS)	**Measure:** *process effectiveness.* ***Measurement and Metric Selection:*** Defects: Consolidated defects from the Assembly Areas, Sensors, Cables. On Time Delivery (OTD): Consolidated on time delivery to the promise date. ***Method for Collection & Use of Data:*** Quality Data is collected from D3 MRP System

QUALITY POLICY

See DP07-0103 “Quality Policy Statement”

QUALITY SYSTEM OBJECTIVES

The Quality System Objectives are found in the current Management Review.

PROCESS METRICS

Order Review & Planning:

These metrics are found in the current Department & Management Reviews.

Design Engineering:

These metrics are found in the current Department & Management Reviews.

Purchasing:

These metrics are found in the current Department & Management Reviews.

Production:

These metrics are found in the current Department & Management Reviews.

Section 1: Scope of the Quality Management System

General

To determine and establish the scope of the QMS, Dytran Instruments determined the boundaries are the buildings that house our organization, the applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company.

The scope is available and maintained as documented information stating the products and services covered by the QMS. Dytran Instruments applies all the requirements of AS9100:2016 and ISO/IEC 80079-34 when they are applicable within the determined scope of the QMS.

AS9100 Certification Scope:

The design and manufacture of Piezoelectric and DC MEMS sensors for measurement and monitoring. The product line includes Smart Sensors for machinery diagnostics, Accelerometers, 6DOF sensors, Dynamic Force Sensors, Pressure Transducers, Accessories and Support Electronics.

Application:

There are no sections of the standard found to be non-applicable at this time.

Section 2: Normative Reference

The following documents were used as reference during the preparation of the Quality Management System:

- International Aerospace Quality Group IAQG, AS9100:2016 - Quality Management Systems - Aerospace Requirements
- International Organization for Standardization, ISO/IEC 80079-34 – Explosive Atmosphere Part 34: Application of Quality Systems for Equipment Manufacture

Section 3: Terms and Definitions

Terminology and definitions specific to a process that are not broadly understood are described in the definition section of any procedures or work instructions that are used in the control of that process.

The following information gives highlights and basic information on how requirements of the various sections of the standard are met. This information is only a summary and not meant to be a detailed or comprehensive overview.

Section 4: Context of the Organization

4.1 Understanding the Organization and Its Context

Dytran Instruments has developed an understanding of its organization and context through the development of our Quality Policy, the diagrams in this manual, the scope in section 1 of this manual, SWOT (Strengths-Weaknesses-Opportunities-Threats) Analysis, and discussions during Management Reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The information in this section is reviewed on a periodic basis during Management Review and is modified as necessary.

The understanding of needs and expectations of interested parties referred to as “customers” is performed in accordance with procedures DP07-0701 Customer Related Processes and DP07-0801 Customer Satisfaction Process. A list of these interested parties is maintained in our MRP System (D3/Pick).

Another class of interested party is our suppliers. Suppliers are controlled in accordance with procedure DP07-0703 Vendor Selection and risk from the supply chain is considered during the Risk Mitigation process. A list of these interested parties is maintained in our Approved Vendors List.

At this time, the following legal requirements apply to the Dytran Instruments quality system on a case by case basis when applied to the contract or purchase order by the customer: ITAR, DPAS, DFAR & FAR. When any of these legal requirements are applied to an order/contract, the regulatory body that governs the applied legal requirement(s) is an “interested party.”

Dytran Instruments manages its operations through KPI’s and objectives. These objectives and KPI’s are managed and monitored in Management Review Meetings.

Environmental Regulations:

Products or parts supplied by Dytran Instruments shall not contain any product, material or substance prohibited by the legislation or regulations applicable in the United States, or other national and global regulations when applicable to the contract or required by its customers, e.g. REACH, RoHS, etc. Dytran Instruments ensures that when appropriate, its customers are informed of the presence in the product of hazardous substances to ensure a high level of protection of human health and the environment from chemical substances.

Conflict Mineral:

When required by contract, Dytran Instruments will provide its customers with a written certification as to the presence of “Conflict Minerals” contained in or used in the production of the items it provides, the country of origin of such “Conflict Minerals” as defined by the Dodd-Frank Wall Street Reform and Consumer Protection Act. “Conflict Minerals,” or 3TG as defined in Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, are:

- Coltan for tantalum
- Cassiterite for tin
- Wolframite for tungsten
- Gold

Any other derivatives or any other mineral or its derivatives determined by the Secretary of State to be financing conflict in the Democratic Republic of the Congo or an adjoining country.

4.3 Determining the Scope of a Quality Management System

The scope of the Quality Management System has been determined in section 1 of this Manual and illustrated in the DP07-0201 Interaction of Processes diagram.

4.4 Quality Management System and Its Processes

The Quality Management System and its processes are illustrated in DP07-0201 Interaction of Processes diagram and the Core Process Diagrams in this manual. This Quality Manual meets the requirements of AS9100 (latest revision) section 4.4.2.

Section 5: Leadership

5.1 Leadership and Commitment

5.1.1 General

Top Management has developed and implemented procedure DP07-0204 Management Responsibility and Authority. Top Management has developed this manual including its diagrams, holds Management Review meetings, performs SWOT Analysis, and assures that applicable information is communicated to personnel. SWOT Analysis will be accomplished during management review of the Core Processes identified and defined in Core Process Diagrams 1 through 4. Furthermore, Top Management has demonstrated their commitment through the development of the Quality Policy, Objectives, Process Metrics, Mission and Values statement documented in this manual.

5.1.2 Customer Focus

Top Management has ensured that all applicable customer and legal requirements are identified and met in accordance with DP07-0701 Customer Related Processes and DP07-0801 Customer Satisfaction Process. Risks that can affect product conformity are assessed using the process risk management tool. Objectives programs are used for maintaining acceptable performance in regard to both product conformity and on time delivery.

5.2 Policy

5.2.1 Establishing the Quality Policy

The quality policy is documented in DP07-0103.

5.2.2 Communicating the Quality Policy

The Quality Policy is posted at predetermined locations throughout the facility. All personnel are made aware of the Quality Policy.

5.3 Organizational, Roles, Responsibilities and Authorities

The roles responsibilities and authorities for Dytran Instruments have been documented in the organizational chart, Job descriptions, procedures, work instructions, and the Core Process Diagrams.

The Quality Assurance Manager has been appointed as the Management Representative and has the following roles and responsibilities:

- Ensuring that the QMS conforms to the requirements of AS9100:2016 standard
- Ensuring that the processes are delivering their intended outputs
- Reporting on the performance of the QMS on opportunities for improvement and for reporting to top management
- Ensuring the promotion of customer focus throughout the organization
- Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented
- The organizational freedom and unrestricted access to top management to resolve quality management issues

The Configuration Management Manager has been appointed as the ATEX Representative and has the following roles and responsibilities:

- Ensuring that the QMS conforms to the requirements of ISO/IEC 80079-34 standard
- The effective coordination of activities with respect to products intended for use in potentially explosive atmospheres.
- The need to liaise with the notified body responsible for the issue of the EC type-examination certificate with respect to any proposed change to the design defined in the EC type-examination certificate and the technical documentation

- The need to liaise with the notified body responsible for the assessment of the quality system with respect to intended updating of the quality system
- Authorizing and Maintaining the EC Declaration of Conformity
- The authorizing of initial approval and changes to related drawings
- The authorization of concessions
- Informing its customers of any applicable special conditions for safe use and any schedules of limitations
- Quarterly review ATEX standards

Section 6: Planning

6.1 Actions to Address Risks and Opportunities

Risk based thinking is demonstrated by the use of SWOT Analysis and process risk analysis as described in procedure DP07-0711 Risk Management Procedure.

6.2 Quality Objectives and Planning to Achieve Them

Quality objectives are documented in the current Management Review. They are controlled using Objective Programs.

6.3 Planning of Changes

Changes that could affect the Quality Management System are discussed in Management Review and other meetings held by Top Management and controlled through the use of the Management Review action items list or Continual Improvement process.

Section 7: Support

7.1 Resources

7.1.1 General

Top management assures the provision of resources necessary to maintain the Quality Management System and the organization in general. Some of these resources are determined through SWOT analysis, process analysis, Human Factors analysis, internal audits, and during contract review. Some of these resources are described in the Core Process Diagrams in Section 0 of this manual while others are documented at Management Review meetings.

7.1.2 People

Dytran Instruments has determined the personnel necessary to maintain an effective Quality Management System through the establishment of the Organizational Chart and related Job Descriptions.

7.1.3 Infrastructure

Where appropriate, infrastructure is maintained in accordance with DP07-0309 Preventive Maintenance.

7.1.4 Environment for the Operation of Processes

Where appropriate, Dytran Instruments monitors environmental factors such as temperature, humidity, light, and/or any other factors that can affect the conformance of product to requirements. The physical, social, and emotional environments are maintained in order to achieve process and product requirements. Human factors are assessed in accordance with DP07-0711 Risk Management Process.

7.1.5 Monitoring & Measuring Resources

7.1.5.1 General

Monitoring and measuring resources are controlled in accordance with procedure DP07-0706 Control of Monitoring and Measurement Equipment.

7.1.5.2 Measurement Traceability

Measurement traceability is controlled in accordance with procedure DP07-0706 Control of Monitoring and Measurement Equipment.

7.1.6 Organizational Knowledge

The information in this section is reviewed on a periodic basis during Management Review and is modified as necessary.

Dytran Instruments has determined the knowledge necessary for the operation of its processes to achieve conformity to product requirements through the development of this Quality Manual, performing SWOT, Process Risk and other assessments. This knowledge is documented in Procedures, Work Instructions, core process diagrams, the training matrix and Job Descriptions. Organizational knowledge (procedures, Work Instructions, etc…) is updated when changes are made to the system or continual improvement actions warrant it in accordance with DP07-0803 Corrective Action, DP07-0804 Preventative Action, and DP07-0312 Continual Improvement Process. Organizational knowledge also includes “Experiential or Tribal Knowledge” that resides in the personal knowledge of specific individuals. In some ways, this knowledge is protected and discussed in Management Review meetings and action is taken when appropriate. Personnel are encouraged to gain knowledge through attending various training by subject matter experts and consultants that is related to their job duties and/or relevant processes.

7.2 Competence

Dytran determines the necessary competence for personnel performing work affecting product quality, provides training or takes other actions to satisfy these needs, evaluates the

effectiveness of the actions taken, ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, experience, training, skills, and experience in accordance with procedure DP07-0601 Employee Training and Development.

7.3 Awareness

All personnel who are key for Dytran Instruments are made aware of the quality policy, the quality objectives, their contribution to the effectiveness of the Quality Management System, the implications of not conforming with the Quality Management System requirements, relevant Quality Management System documented information and changes thereto, their contribution to product or service conformity, their contribution to product safety, and the importance of ethical behavior through an initial on board training given within the first 90 days of their employment. The initial QMS Awareness for new hires is documented on the 172-0288 New Hire QMS Training form. This process is controlled in accordance with procedure DP07-0601 Employee Training and Development.

7.4 Communication

The information in this section is reviewed on a periodic basis during Management Review and is modified as necessary.

Internal Communication:

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, Management Review, Internal Audits, and other routine business communication. Email and bulletin board postings are also utilized to communicate and raise awareness of important topics such as the policy, objectives, metric graphs and other notifications.

External Communication:

The Management Representative of Dytran Instruments will communicate with regulatory authorities when required, and to customers in regard to information pertaining to their orders and the Dytran Instruments Quality Management System. Internally, Dytran Instruments communicates with its personnel through posting policies, objectives, graphs, and other pertinent information.

Dytran Instruments shall provide right of access for its customers, its customers' customers, statutory 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.

Dytran Instruments will communicate, when appropriate, and make proper provision for the health, safety, and welfare of its people, visitors, contractors, customers, and those in the community who may be affected by our activities.

Changes to the Dytran Instruments that may affect quality, delivery and / or finance, shall be communicated in writing by the Management Representative to its customers prior to

incorporation of such changes. These changes may include; company ownership, company name, manufacturing facility location, quality approvals, changes in product and/or process, changes of sub tiers and where required, obtain customer and/or regulatory approval.
If there is any change in the status of our AS9100 certification, the Management Representative of Dytran Instruments will notify its customers within 2 business days of receiving notification of that change from the registrar.

The Management Representative of Dytran Instruments will notify its customers and regulatory authorities of any escapes within 24 hours of discovery.

If there are any planned changes identified that could affect quality of the product, the customer will be notified prior to the affectivity of the change by the Management Representative of Dytran Instruments.

Any forms or methods required by the customer to notify them of such changes will be utilized.

Also see procedures DP07-0701 Customer Related Processes and DP07-0801 Customer Satisfaction Process for communications related to orders or customer feedback.

7.5 Documented Information

7.5.1 General

Dytran Instruments has developed this manual, the procedures referenced in this manual, work instructions, forms, and logs in order to maintain and control our Quality Management System.

7.5.2 Creating and Updating

The process for creating and updating documented information is controlled in accordance with procedure DP07-0401 Control of Documents.

7.5.3 Control of Documented Information

Documented information is controlled in accordance with procedure DP07-0401 Control of Documents and DP07-0402 Control of Records.

Section 8: Operation

8.1 Operational Planning and Control

Operational planning and control is achieved in accordance with DP05-0210 Job Traveler Process, DP07-0303 Traveler Release process, and the Order Review and Planning Core Process Diagram. Planning for outsourced manufacturing and work transfers is controlled in accordance with procedure DP07-0709 Control of Work Transfer. Program management is controlled in accordance with DP07-0710 Program Management Process.

*Marketing must be notified of any changes

8.1.1 Operational Risk Management

Operational risk management is performed in accordance with DP07-0711 Risk Management Process.

8.1.2 Configuration Management

Configuration Management is controlled in accordance with procedures DP07-0403 Configuration Management, DP05-0101 Numbering System, DP05-0205 Document Control Processing, and DP05-0209 Design Process.

8.1.3 Product Safety

Controls necessary to maintain product safety are developed as appropriate when identified during process risk assessments in accordance with procedures DP05-0209 Design Process & DP07-0711 Risk Management Procedure.

8.1.4 Prevention of Counterfeit Parts

Prevention of counterfeit parts is performed in accordance with DP07-0808 Control of Counterfeit Parts/Materials.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers is performed in accordance with procedure DP07-0801 Customer Satisfaction Process and the Order Review and Planning Core Process Diagram.

Also, see section 7.4 of this manual.

8.2.2 Determining the Requirements for Products and Services

The determination of requirements for products and services is performed in accordance with procedure DP07-0701 Customer Related Processes and the Order Review and Planning Core Process Diagram.

8.2.3 Review of the Requirements for Products and Services

Review of the Requirements for Products and Services is performed in accordance with procedure DP07-0701 Customer Related Processes and the Order Review and Planning Core Process Diagram.

8.2.4 Changes to Requirements for Products and Services

Changes to requirements for products and services are performed in accordance with

procedure DP07-0701 Customer Related Processes and the Order Review and Planning Core Process Diagram.

8.3 Design and Development of Products and Services

The requirements for Design & Development are controlled in accordance with procedure DP05-0209 Design Process, Section 8.1.2 of this manual, and the Design Core Process Diagram.

8.4 Controls of Externally Provided Processes, Products, and Services

8.4.1 General

Controls of externally provided processes, products and services are performed in accordance with procedure DP07-0704 Purchasing Process and the Purchasing Core Process Diagram. Dytran Instruments is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer. Dytran Instruments ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used and that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met. High level supply chain risk is assessed in the SWOT process while specific risk from suppliers is controlled in accordance with procedure DP07-0810 Supplier Risk Assessment.

8.4.2 Type and Extent of Control

Type and extent of control for externally provided processes, products and services are described in procedures DP07-0203 Procurement Quality Requirements, DP07-0703 Vendor Selection, DP07-0704 Purchasing Process, DP07-0806 Monitoring/Measurement of Product-Processes, and DP07-0808 Control of Counterfeit Parts/Materials and the Purchasing Core Process Diagram.

8.4.3 Information for External Providers

Information for external providers is controlled in accordance with procedures DP07-0203 Procurement Quality Requirements, DP07-0703 Vendor Selection, and the Purchasing Core Process Diagram.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Control of production and service provision is achieved by the use of Shop Orders/Travelers in accordance with procedures DP07-0809 Control of Production & Service Provision, DP05-0210 Job Traveler Process, DP07-0303 Traveler Release Process, DP07-0304 Traveler-Work Order Split Process, DP07-0806 Monitoring/Measurement of Products-Processes, and the Production Core Process Diagram. Work instructions are developed

when necessary to assure conformance to requirements. Dytran Instruments has implemented a FOD program in accordance with DP07-0308 Foreign Object Debris FOD Management.

8.5.1.1 Control of Equipment, Tools and Software Programs

Equipment, tools and software programs that are used to automate, control, monitor or measure production processes are validated by running a “First Piece” to confirm that the output meets product conformity requirements. These requirements are controlled in accordance with procedures DP05-0214 Software Design Process, DP05-0212 CAD Files for NC Programs, and DP07-0307 Control of Dytran Tooling.

8.5.1.2 Validation and Control of Special Processes

Dytran Instruments controls special processes by the use of process specific Work Instructions and by validating and revalidating both process personnel and equipment. Dytran Instruments does outsource some special processes and controls these outsourced special processes by using customer approved sources or third-party certified sources (as applicable) when customers do not have approved sources they require to be used for the process.

8.5.1.3 Production Process Verification

Production processes are verified in accordance with DP07-0806 Monitoring/Measurement of Products/Processes using a representative item from the first production run of a new part or assembly to verify that the process and tooling are capable of producing conforming parts. This process is recorded on a First Article Inspection Report. Verification is repeated when changes occur that could invalidate the original results. Configuration Management including assurance that the correct revisions of all drawings and other production documents were used shall be performed.

8.5.2 Identification and Traceability

Identification and traceability of product is maintained and controlled in accordance with DP07-0811 Product Identification and Traceability. The configuration of the product shall be identified and managed, including traceability when required by the customer.

8.5.3 Property Belonging to Customers or External Providers

Property belonging to customers or external providers is controlled in accordance with DP07-0707 Customer Property.

8.5.4 Preservation

Dytran Instruments preserves the product in accordance with procedure DP07-0705 Preservation of Product during internal processing and delivery to the intended destination

in order to maintain conformity to requirements specified in customer contract. Where appropriate, instructions are used to control specific aspects of this process. When applicable, customer packaging specifications are flowed down to any sub-contractor or off-site packaging service. Dytran Instruments has implemented a FOD program in accordance with DP07-0308 Foreign Object Debris FOD Management.

8.5.5 Post-Delivery Activities

Post-delivery activities as they apply to Dytran Instruments are controlled in accordance with procedure DP07-0316 Processing of Returned Product and DP07-0805 Control of Nonconforming Products.

8.5.6 Control of Changes

Control of changes is performed in accordance with DP05-0210 Job Traveler Process. Also see section 7.4 of this manual.

8.6 Release of Products and Services

Dytran Instruments monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Final inspection before shipping is controlled in accordance with DP07-0324 Outgoing Shipping Inspection.

Evidence of conformity with the acceptance criteria is maintained and documented to the lot that was measured and/or tested. If testing and/or measuring activities are outsourced, the supplier is selected and evaluated in accordance with section 8.4 of this manual and the Purchasing Core Process Diagram.

When Dytran Instruments uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use. The plan precludes the acceptance of lots whose samples have known non-conformities. When required, the plan is submitted for customer approval.

8.7 Control of Non-Conforming Outputs

Control of Non-Conforming Outputs is performed in accordance with procedure DP07-0805 Control of Nonconforming Products.

Section 9: Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Monitoring, measurement, analysis and evaluation are controlled by the use of objective programs, Internal Audits, Management Reviews, and KPI's (Key Performance Indicators). Process Control is performed in accordance with DP07-0318 Inspection Requirements.

9.1.2 Customer Satisfaction

Customer Satisfaction is measured by the monitoring of the Product Acceptance and On Time Delivery Objectives and where appropriate through customer surveys and/or report card monitoring.

9.1.3 Analysis and Evaluation

a) Conformity of products and services is analyzed and evaluated in accordance with section 8.6 of this manual and product conformity objective programs.
b) Customer satisfaction is analyzed and evaluated in accordance with product conformity objective programs, on time delivery objective programs and where appropriate through customer surveys and/or report card monitoring.
c) The performance and effectiveness of the QMS is analyzed and evaluated in accordance with Procedure DP07-0204 Management Responsibility and Authority, Procedure DP07-0802 Internal Audits, through objective programs and KPI's.
d) Planning is analyzed and evaluated in accordance with the Order Review & Planning Core Process Diagram, section 8.6 of this manual and product conformity objective programs for production planning and through internal audits, Management Reviews, and our continual improvement process for QMS planning.
e) The effectiveness of actions to address risk and opportunities is analyzed and evaluated through our continual improvement process and in Management Review.
f) The performance of external providers is analyzed and evaluated through our supplier performance KPI's and monitored in Management Review.
g) The need for improvements to the QMS is analyzed and evaluated during Management Reviews.

9.2 Internal Audit

Internal Audits are performed in accordance with procedure DP07-0802 Internal Audits.

9.3 Management Review

9.3.1 General

Management Reviews are performed in accordance with DP07-0204 Management Responsibility and Authority.

9.3.2 Management Review Inputs

The required inputs for Management Review are controlled using a Management Review Agenda in accordance with procedure DP07-0204 Management Responsibility and

Authority.

9.3.3 Management Review Outputs

The outputs from Management Review are monitored and tracked by use of the Management Review Action Items List. These outputs are also considered for inclusion in the continual improvement process in accordance with procedure DP07-0204 Management Responsibility and Authority.

Section 10: Improvement

10.1 General

Improvement projects are developed as a result of SWOT analysis, process risk analysis (in the form of risk mitigation), through the development of corrective actions resulting from non-conformities and opportunities for improvement found in internal audits other corrective actions (both internal and from customers), and actions arising out of Management Review meetings.

10.2 Non-Conformity and Corrective Action

The non-conformity and corrective action process is performed in accordance with procedures DP07-0803 Corrective Action and DP07-0804 Preventative Action.

10.3 Continual Improvement

Continual improvement is performed in accordance with procedure DP07-0312 Continual Improvement Process.

QMS Procedures:

A list of Sales Procedures can be found in DP04-0000 Index.

A list of Engineering Procedures can be found in DP05-0000 Index.

A list of Quality Procedures can be found in DP07-0000 Index