Quality Policy Manual

Matric
2099 Hill City Road
Seneca, PA 16346

www.matric.com

Statement of Authority

Matric recognizes its responsibilities to fully comply with all contractual, statutory and regulatory requirements. Toward this end, Matric has developed a comprehensive Quality Management System (QMS). This system establishes company-wide controls that minimize the possibility of compromises, which could affect product quality and reliability. The Quality Management System is complete and responsive to all current requirements of the ISO 9001 "Quality Management System – Requirements," EN 80079-34 "Explosive Atmospheres – Application of Quality Systems for Equipment Manufacture," ATEX Directive 2014/34/EU "Equipment for Potentially Explosive Atmospheres," AS9100 "Requirements for Aviation, Space and Defense Organizations," ISO 13485 "Medical Devices Quality Management Systems Requirements for Regulatory Purposes" and any applicable customer, statutory and regulatory requirements that apply.

This Matric Quality Policy Manual provides the foundation for the quality management system which is implemented through the associated procedures and work instructions. These procedures and work instructions are directive documents which define specific actions and assign responsibility for these actions as to who, where, when and how each procedure is to be performed. Compliance with the Quality Policy Manual and the associated quality procedures and work instructions is mandatory for all associates.

The Matric Director of Quality Services has been appointed as the Management Representative and delegated the responsibility and authority for implementation of the Quality Management System, including control of the Quality Policy Manual, the issuance of procedures and work instructions, and liaison with internal and external parties regarding the Quality Management System.

A representative (an "Authorized Person") has been appointed to: effectively coordinate activities with respect to products intended for use in potentially explosive atmospheres, effectively interface with the body conducting document reviews, where appropriate, review and approve concessions related to products with an Ex certificate.

Richard E. Turner, Jr.
President and Chief Executive Officer
Matric

Matric Quality Management System

1. General

1.1 General

The Matric Quality Management System:

a) recognizes the need to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of this system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements, and

The Matric Quality Management System is achieved through identified operational processes and using risk-based thinking to identify opportunities to mitigate risk and take advantage of opportunities within these processes.

1.2 Application

Matric's Quality Management System, as defined in this Quality Policy Manual and referenced documents, applies to all Matric operations and products.

1.3 Scope

Design, Manufacture and Aftermarket Service of electronic, electro-mechanical and cable assemblies; serving a wide range of industries, including commercial, industrial, medical and harsh environment (Intrinsic Safety rated).

No exclusions are taken from ISO 9001, AS9100, EN 80079-34 or ATEX Directive 2014/34/EU requirements. Exclusions are taken from ISO 13485 sections 7.5.2b,c,d, 7.5.3, 7.5.5, 7.5.7, 7.5.9.2, 8.2.6 (para 4) and 8.3.3 (para 2) as Matric does not perform sterilization, installation and does not design, manufacture or service active implantable or implantable medical devices.

2. Normative Reference

For dated references to standard documents, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

3. Terms and Definitions

The following terms are used to describe the supply chain:

supplier → Matric (manufacturer) → customer

Quality Management System will be referenced as the QMS throughout this document.
Requirements can and may include customer, organizational, QMS, statutory and regulatory requirements.
Documented Information is a reference to all controlled information necessary for the effectiveness of the QMS. Within this manual and referenced procedures, control of documents and records are still defined as such.

Throughout this manual:

- The terms and definitions in ISO 9000 apply.
- the term "product" can also mean "service."

Note: Refer to data 03-01 for other related definitions.

4. Quality Management System and the Context of the Organization

4.1 General Requirements

a) Matric has established a QMS that is documented in this Quality Policy Manual and the associated procedures and work instructions. Matric has implemented and maintains this QMS and is committed to continually improving its effectiveness. Matric's QMS addresses all applicable requirements. This QMS ensures that the product conforms to the type described in the Ex certificate and the technical documentation.

b) Matric shall determine, monitor and understand both the external and internal issues that are relevant to the organization.

c) Matric will define and understand the needs and expectations of the stakeholders.

Specifically:

a) Matric has identified the processes needed for the QMS (including process inputs and outputs 4.4a) and their application throughout the organization.
b) Matric documents the operation of these processes through operational process diagrams and process metrics. These metrics and the results of internal audits are reviewed regularly to ensure these processes achieve their intended results.

PROCESS MATRIX - Black text is ISO 13485 clauses, Red text is ISO 9001, AS9100 clauses											
		1	2	3	4	5	6	7	8	9	10
Exclusions, if any, are listed below -{exclusion must be justified in this Quality Policy Manual and will be verified throughout the processes during all registration audits} No exclusions P = Primary Responsibility S = Secondary Responsibility		Management Responsibility	Manufacturing	Planning/ Scheduling	Employee Hiring & Development	RFQ/Contract review/Order entry	Warehouse/ Pack & Ship	Engineering Design & Development	Aftermarket Service	Procurement	Inspection & Test
4.1, 4.1-4.4	General Requirements, Context of the Organization, Understanding the Needs of Stakeholder, Scope, QMS requirements	P									
4.2, 7.5	General Documentation Requirements	P	P	P	P	P	P	P	P	P	P
4.2.2	Quality Manual	P									
4.2.3, 4.2.4, 7.5	Medical Device file, Control of Documents	P	S	S	S	S	S	P	S	S	S
4.2.5, 7.5	Control of Records	P	S	S	S	S	S	S	S	S	S
5.1, 5.1	Management Commitment, Leadership	P									
5.2, 5.1.2	Customer Focus	P				P					
5.3, 5.2	Quality Policy	P	P	P	P	P	P	P	P	P	P
5.4.1, 6.2, 6.3	Quality Objectives (Planning)	P	P	P	P	P	P	P	P	P	P
5.4.2, 6.1	QMS Planning including Risks & Opportunities	P									
5.5, 5.3, 7.4	Responsibility, Authority and Communication	P									
5.6, 9.3	Management Review	P									
6.1, 7.1.1	Provision of Resources	P									
6.2, 7.1.2	Human Resources	S	S	S	P	S	S	S	S	S	S
6.2, 7.1.6, 7.2, 7.3	Competence, Awareness, Training and Organizational Knowledge	P	P	P	P	P	P	P	P	P	P
6.3, 7.1.3	Infrastructure	P	S	S	P	S	S	S	S	S	S
6.4, 7.1.4	Work environment and contamination control	P	S	S	S	P	S	S	S	S	S
7.1, 8.1, 8.2	Planning of Product Realization, Operational Planning & Control	P			P	P					
7.2, 8.2.1	Customer-Related Processes, Communication & Review of the requirements related to product					P		P	P		
7.3, 8.3	Design and Development					S		P			
7.4, 8.4	Purchasing, Control of Externally Provided Processes, Products and Services					S				P	
7.5, 8.2, 8.2.1-8.2.4, 8.5.1, 8.5.6, 8.5.5, 8.6, 8.7	Requirements & Control of Production and Service, Release of Products and Services, Post Delivery Activities and Control of Nonconforming Outputs		P						P		
7.5.6, 8.5.1	Validation of Processes for Production and Service		P						P		
7.5.8, 7.5.9, 8.5.2	Identification and Traceability		P				P	S	P	P	P
7.5.10, 8.5.3	Customer Property		P				S	S	P	P	P
7.5.11, 8.5.4	Preservation of Product		P				P		P		
7.6, 7.1.5	Control of Monitoring and Measuring Devices		P				S	S	S	S	P
8.1, 9.1, 9.1.1	Measurement, Analysis and Improvement	P			S	S		S		S	
8.2.1, 9.1.2	Customer Satisfaction and Feedback	P				P					
8.2.2	Complaint Handling	P				S					
8.2.4, 9.2	Internal Audit	P	S	S	S	S	S	S	S	S	S
8.2.5, 9.1	Monitoring and Measurement of Processes	P	P	P	P	P	P	P	P	P	P
8.2.6, 9.1	Monitoring and Measurement of Product		P					S	P		P
8.3, 8.7, 10.2	Control of Nonconforming Material (Outputs)	S	P				P	S	P	S	P
8.4, 9.1.3	Analysis of Data, Evaluation	P	S	S	S	S	S	S	S	S	S

PROCESS MATRIX - Black text is ISO 13485 clauses, Red text is ISO 9001, AS9100 clauses											
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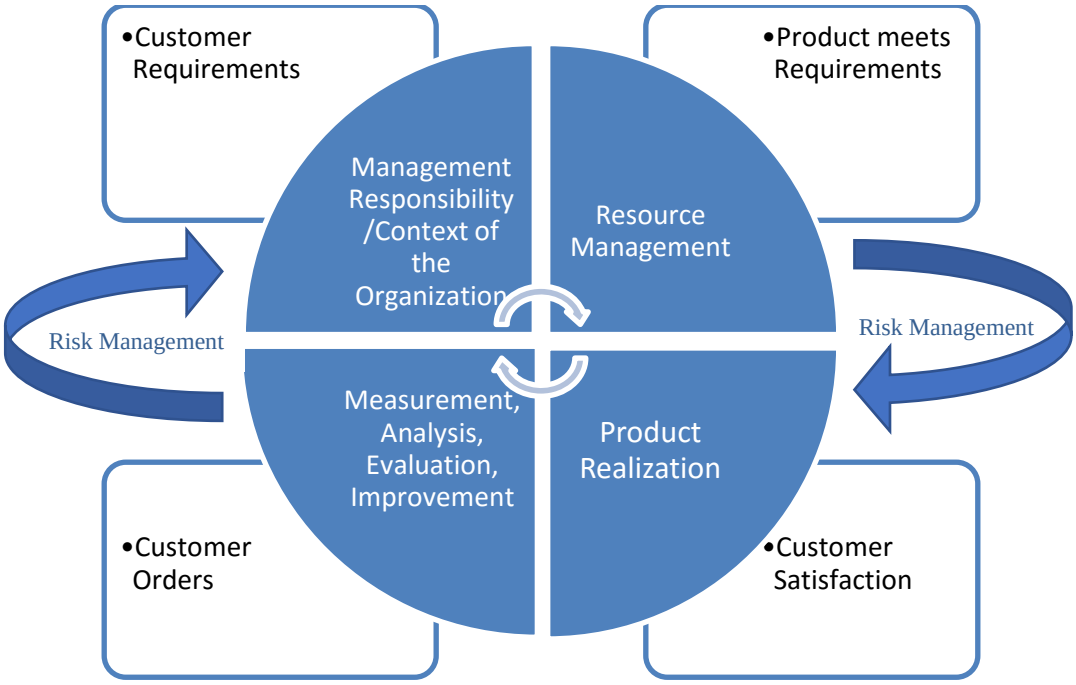
Exclusions, if any, are listed below -{exclusion must be justified in this Quality Policy Manual and will be verified throughout the processes during all registration audits} No exclusions P = Primary Responsibility S = Secondary Responsibility		**Management Responsibility**	**Manufacturing**	**Planning/ Scheduling**	**Employee Hiring & Development**	**RFQ/Contract review/Order entry**	**Warehouse/ Pack & Ship**	**Engineering Design & Development**	**Aftermarket Service**	**Procurement**	**Inspection & Test**
8.5.1, 10.3	Continual Improvement	P	S	S	S	S	S	S	S	S	S
8.5.2, 10.2	Corrective Action	P	S	S	S	S	S	S	S	S	S
8.5.3	Preventive Action	P	S	S	S	S	S	S	S	S	S

c) Matric has determined the sequence and interaction of these processes. Reference the following sections of this manual for the sequence and interaction of specific processes:
- section 5.6 for the management review process,
- section 6 for resource management processes,
- section 7 for sequence & interaction of product realization processes,
- section 8 for the measurement, analysis and improvement processes,

Sequence and Interaction of Major Processes



d) Matric has determined the criteria and methods needed to ensure that both the operation and control of these processes are effective (refer to sections 7.1, 7.3.3(c), 7.4.1 [criteria for selection], 7.5.2 of this manual).
e) Matric ensures the availability of resources and information necessary to support the operation and monitoring of these processes (refer to section 6 of this manual),
f) Matric monitors, measures and analyzes these processes (refer to section 8.2.3 of this manual),
g) Matric assigns responsibilities and authorities to the processes
h) Matric has implemented actions necessary to evaluate and achieve planned results, maintain effectiveness of and continually improve these processes. Continual improvement includes quality objectives, corrective and preventive actions, internal quality audits, evaluating the effectiveness of actions to address risks and opportunities, monitoring feedback indicators of customer satisfaction, improvement items resulting from Operation Group meetings, Management Reviews and actions initiated by the Opportunity for Improvement system (suggestion system).

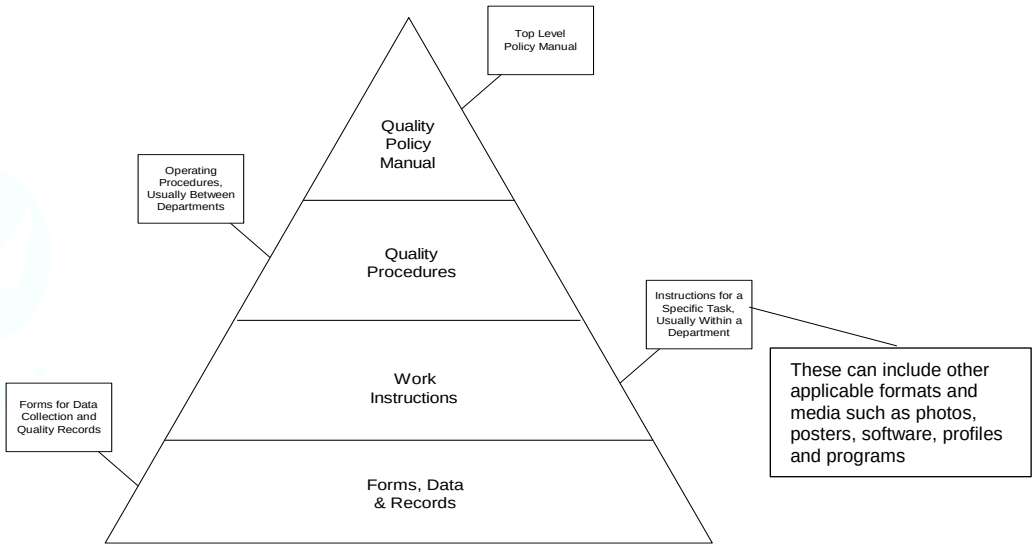
Matric manages these processes in accordance with this documented QMS, which complies with the current requirements of ISO 9001, AS 9100, ISO 13485, EN 80079-34 and ATEX Directive 2014/34/EU.

4.1.1 Control of Outsourced Processes

When a process that Matric needs for its QMS is performed by an external party, that process is considered to be outsourced. This includes processes for management activities, provision of resources, product realization, measurement, analysis and improvement. When any process that affects product conformity with requirements is outsourced, Matric ensures control over such processes. In ensuring such controls, Matric continues to be responsible for all customer, statutory and regulatory requirements. The type and extent of control applied to the process is influenced by factors such as:

a) The potential impact of the outsourced process on Matric's ability to provide product that conforms to requirements,
b) The degree to which the control for the process is shared,
c) The capability of achieving the necessary control through the Purchasing Process defined in section 7.4. See 7.4.1 for additional controls for outsourced product realization processes.

4.2 Quality System Documentation (Documented Information)



DOCUMENTATION PYRAMID

4.2.1 General

Matric refers to all controlled documentation and records required by the International Standards and used to ensure the effectiveness of the QMS as **documented information**. This documented information may be presented in any format or media as applicable to achieve the intended outcome and that can be understood by those persons performing the task.
Matric's QMS includes the following documented information:

a) the Matric quality statement and quality policy are documented in section 5.3 of this Quality Policy Manual and as a separate document in Data 05-01.
Quality objectives are established and documented annually (refer to section 5.4.1 of this manual).
b) this Quality Policy Manual,
c) documented procedures referenced in this Quality Policy Manual, in conformance with the ISO 9001, AS9100, ISO 13485, EN 80079-34 and ATEX Directive 2014/34/EU standards,
d) procedures, work instructions and records needed to ensure the effective planning, operation and control of its processes,
e) forms, data and records referenced in this quality assurance manual, procedures and work instructions.
f) any other documentation specified by national or regional regulations.
g) Matric ensures that personnel have access to, and are aware of, relevant QMS documentation and changes.

Matric procedure QOM 04-01 details procedures and controls for quality system documentation.

NOTE: Matric does not currently design, manufacture, install or service end-item medical devices and has no plans to do so. Therefore, files are not maintained by medical device type or model.

4.2.2 Quality Policy Manual

The Quality Policy Manual outlines the structure of the documentation used in the QMS.

Matric has established and maintains this Quality Policy Manual that includes:
a) the application (section 1.2) and scope (section 1.3) of the QMS, including details and justification for any exclusions and/or non-application.
b) the hierarchical structure of the QMS documentation.
c) reference to documented procedures established for the QMS,
d) a description of the interaction between the processes of the QMS; refer to sections 4.1 b), 5.6, 6 and 7 of this manual,
e) approval signature of Matric's Chief Executive Officer.

4.2.3 Creation and Control of Documented Information

Documents required by the Matric QMS are controlled.
Matric procedures QOM 04-01 & QOM 07-06 define the controls needed:
a) to review and approve documents for adequacy and suitability prior to issue,
b) to ensure documents include identification and a description
c) to review and update as necessary and re-approve documents,
d) to ensure that changes and the current revision status of documents are identified,
e) to ensure that relevant and suitable versions of applicable documents are available at points of use and these are adequately protected from improper use,
f) to distribute, access and retrieve documents,
g) to ensure that documents remain legible and readily identifiable,
h) to prevent the deterioration or loss of documents,
i) to ensure that documents of external origin are identified and their distribution is controlled,
j) to prevent the unintended use of obsolete documents and to apply suitable identification if they are retained for any purpose. The period for which obsolete documents shall be retained is defined. This period shall ensure that documents which are used in medical devices are available for at least the lifetime of the medical devices, and not less than the retention period of any resulting record (see 4.2.4), or as specified by the relevant regulatory requirements.

Changes and updates to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information on which to base its decisions.

For products with an Ex Certificate:

a) Technical documentation and manufacturer's documentation are controlled,
b) Documented procedures ensure that information contained within manufacturer's documents is compatible with equipment documents. Matric will not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings.
c) The quality system ensures that no factor (type, characteristic, position, etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified.
d) There is a documented system that refers all related drawings to relevant schedule drawings.
e) Where there are common schedule drawings associated with more than one Ex certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings.
f) Matric maintains a system that enables related drawings and schedule drawings to be clearly identified.
g) Matric documents which Body is responsible for the quality system documentation for each Ex certificate.
h) When equipment drawings or manufacturer's drawings are passed to a third party, it shall be done in a way that is not misleading.
i) Matric has a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specification.

4.2.4 Control of Records

Matric establishes and maintains records to provide evidence of conformity to requirements and of effective operation of the QMS. Records shall remain legible, readily identifiable and retrievable. The controls placed on documented information in section 4.2.3 also apply to records.

Matric maintains records for a period of time at least equivalent to the lifetime of the medical device, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.

Matric maintains records for a product with an Ex certificate for a period of time at least ten years after the product has been placed on the market.

Matric procedure QOM 04-02 *Quality Records* defines controls needed for identification, storage, protection, retrieval, retention time and disposition of records (e.g. those arising from regulatory requirements, customer order, contract review, training records,

inspection and test data, calibration data, sub-contractor evaluation, delivery data), including records that are created by and/or retained by suppliers.

Matric Procedure 04-03 defines the system for controlling documentation of products that have an EC type examination certificate.

NOTE: Matric does not currently design, manufacture, install or service end-item medical devices and does not receive nor maintain confidential health records.

4.2.5 Use of third party (i.e. registrar) Logos and Certificates

Original artwork for third party (i.e. registrar) logos is controlled as a document of external origin. Artwork revisions are to be implemented immediately upon receipt from the third party (i.e. registrar). Artwork must be used in its entirety, without modifications (except as permitted by the issuer). Any application of a registrar's logo or certificate must not imply that a product is certified / registered and must not be misleading. The certification logo may be used to promote the area of the scope of certification (exclusions, if any, must be identified), and it may be used on promotional items.

4.2.6 Sales Literature and Data Sheets

Matric does not create or maintain documents such as data sheets and sales literature for products for aerospace products, medical devices or products with an Ex Certificate,

5 Management Responsibility

5.1 Management Commitment and Leadership

Matric Top Management demonstrates its commitment to the development and implementation of the QMS and maintaining its effectiveness by:

a) communicating to the organization the importance of meeting all requirements, the importance of conforming to the QMS to maintain an effective QMS. This communication is accomplished through documented procedures and work instructions, training (e.g. Continual Quality Improvement Training), informational meetings ("Town Talks") held monthly with all associates, as well as other means.
b) establishing the quality policy,
c) ensuring that quality objectives are established and that these are compatible with the context and strategic direction of the company.
d) promoting the process approach and risk-based thinking
e) conducting management reviews, and
f) ensuring the availability of resources
g) ensuring that the QMS is integrated into the business process.
h) ensuring the QMS achieves its intended results

i) promoting improvement
j) supporting Management roles as it applies to their areas of responsibility

Records of the above activities shall be maintained to provide evidence of this commitment.

5.2 Customer Focus

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see section 7.2.1 and 8.2.1 for details), and also that product conformity and on-time delivery performance are measured with appropriate action taken if planned results are not or will not be achieved. Risks and opportunities that can affect customer satisfaction will be determined and addressed.

5.3 Quality Statement and Quality Policy

Top management has established the Matric quality statement and quality policy:

Quality Statement:

"To do right for our customers, our community, our owners…

We at Matric are committed to continual quality improvement in everything we do, dedicating ourselves to meeting the needs of those relying on us."

Quality Policy:

"Matric is committed to providing safe, effective products and services for electronic applications that meet all known customer performance and reliability requirements. The Matric quality management system is dedicated to using defined techniques and behaviors to continually reduce variation in process and products – satisfying requirements of both internal and external customers. Matric is committed to complying with all applicable statutory and regulatory requirements and maintaining the effectiveness of the quality management system.

We strive to prevent defects by focusing on processes ultimately resulting in better product quality at reduced cost. These results are realized through the effective use of our greatest resource, our people, who are responsible and accountable for the quality of their work.

Matric Associates are committed to rapid organization response, providing our customers with the fastest concept-to-commercialization time in the electronics industry.

Matric will maintain an environment that fosters continual quality improvement in all

areas of its operations."

Top management has ensured this quality policy:

a) is appropriate to the purpose and the context of the Matric organization and supports its strategic direction,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the QMS,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated, understood and applied within the organization,
e) is maintained as documented information
f) is available to all appropriate personnel
g) is reviewed at management review meetings for continuing suitability

5.4 Planning

5.4.1 Quality Objectives

Top management establishes quality objectives (including objectives needed to meet requirements for product) on an annual basis by no later than March 31 of the year (see 7.1.a). The objectives are established at relevant functions and levels within the organization, are measurable and consistent with the quality policy. These objectives will be monitored, communicated and updated as needed.

5.4.2 QMS Planning

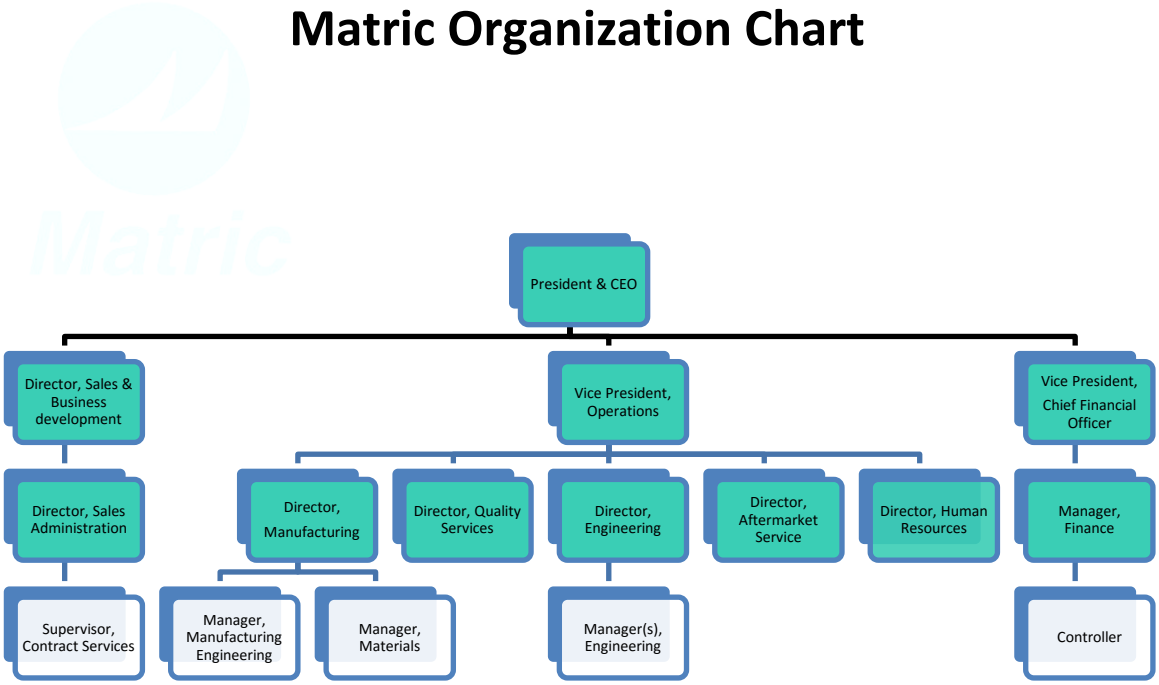
Top management ensures that

a) the planning of the QMS is carried out in order to meet the requirements given in 4.1, as well as the annual quality objectives,
b) the integrity of the QMS is maintained when changes to the QMS are planned and implemented,
c) The responsible department Director / Manager and the Management Representative review and approve all new issues of and revisions to quality system procedures and work instructions
d) Risks and opportunities will be determined and addressed to ensure the QMS meets intended results, enhance desirable effects and reduce undesired effects and achieve improvement. The effectiveness of these actions will be evaluated typically at Management Review meetings.

All the elements, requirements and provisions adopted by Matric in order to ensure compliance of the product with its Ex certificate and technical documentation are documented in a systematic and orderly manner in the form of written policies, procedure and work instructions. The quality system documentation permits a consistent interpretation of quality programs, plans, manuals and records.

5.5 Responsibility, Authority and Communication

5.5.1 Roles, Responsibility and Authority



The Matric organization chart defines the internal organization and reporting relationships.

Top management has ensured that responsibilities and authorities are defined through the organization chart (reference Data 05-03), process matrix (reference section 4.1), job descriptions, procedures and work instructions and are communicated within the organization. Quality Services manages, performs and verifies work affecting quality; to assure independence and authority, Quality Services reports at the same level as the product realization functions Manufacturing Services and Aftermarket Services.

5.5.2 Management Representative

By approval of this Quality Policy Manual, top management appoints the Director of Quality Services as Management Representative who, irrespective of other responsibilities, has responsibility and authority that include:

a) ensuring that processes needed for the QMS are established, implemented and maintained and deliver intended outputs,
b) conformity of the QMS and any changes to the QMS meet the requirements of the International Standards,
c) reporting to top management on the performance of the QMS and any need for improvement (see 8.5)
d) ensuring promotion of awareness of customer requirements throughout the organization, promotion of customer awareness may include news releases, meetings, training, photographs, models and examples of products demonstrating required attributes
e) the organizational freedom and unrestricted access to top management to resolve quality management issues.
f) Liaison with internal and external parties on matters relating to the QMS. This includes interface with the bodies responsible for verification of the quality system with respect to audits and intended updating of the quality system,

5.5.3 Internal Communication

Top management ensures that appropriate communication methods are established throughout the organization and that the communication takes place regarding effectiveness of the QMS. These communication methods include, but are not limited to: metrics board, annual associate appraisal, monthly town-talk meetings with the president (includes semiannual review of quality objectives), daily publication of *Matric Minute*, monthly internal newsletter (*Tradewinds*), e-mail, Quality Alerts, Operations Group meetings (normally held weekly), information board and quality system documentation (Quality Policy Manual, Quality Operations Manual, Work Instructions, Internal Audit Reports, Corrective/Preventive Actions).

5.5.4 Authorized Person

Matric has appointed a representative (an “authorized person”) to be the lead for activities related to products with an Ex certificate, as defined in EN 80079-34 and ATEX 2014/34/EC:
a) The effective coordination of activities with respect to products intended for use in potentially explosive atmospheres,
b) The liaison with the issuer of the Ex certificate (when not issued by Matric) with respect to any proposed change to the design defined in the Ex certificate and the technical documentation,
c) the authorization of initial approval and changes to the related drawings, as applicable,
d) the authorization of concessions (also see 8.3),
e) the customers’ information of any applicable specific conditions of use and any schedules of limitations,

f) the reviewing of Ex certificate and technical documentation and identifying any changes that effect compliance with the certificate.

Engineers are responsible for authorizing initial approval and changes to related drawings, where appropriate. Engineers authorizing such approvals and the Authorized Person are trained on requirements applicable to products with an Ex certificate (reference section 6.2.2 a).

5.6 Management Review Process

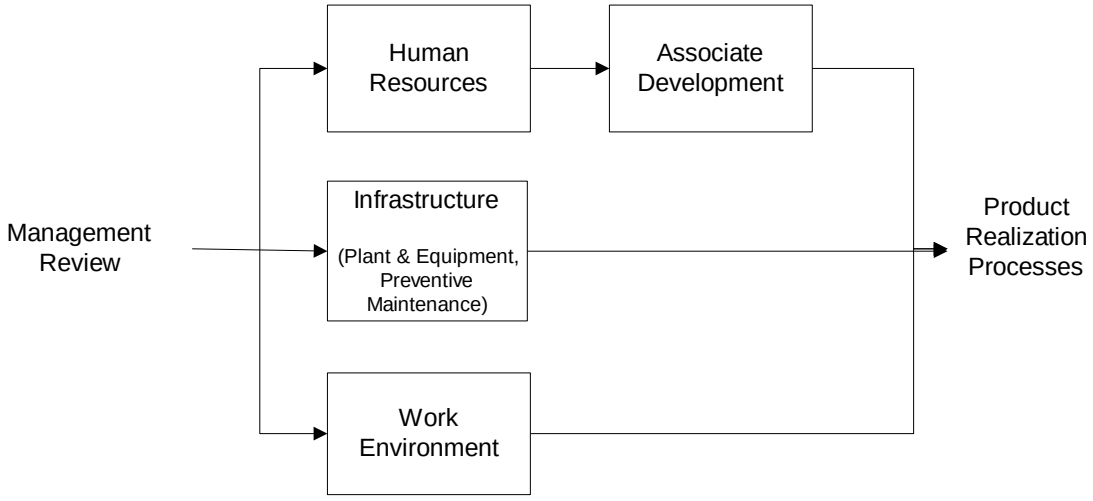
5.6.1 General

Top management reviews the process measures of the organization's QMS at least bimonthly, to ensure continuing suitability of the many processes, adequacy and effectiveness of the overall QMS. The entire quality system will be reviewed at least annually, not to exceed 14 months. This review includes assessing risk and opportunities for improvement and the need for changes to the QMS, including quality policy and quality objectives, and changes in statutory/regulatory requirements.

The management review meeting is chaired by the Chief Executive Officer or, in his absence, by the General Operating Manager. The meeting must be attended by the "authorized person" (reference section 5.5.4) or his deputy. In addition, a quorum of a simple majority of the Operations Group is required. Matric procedure QOM 05-06 details the procedure for Management Review.

Records of the management reviews shall be maintained (see 4.2.4) in the computer database perennially

6 Resource Management



Sequence & Interaction of Resource Management Processes

6.1 Provision of Resources

Matric determines and provides the resources needed

a) to implement and maintain the QMS and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements
c) to meet regulatory requirements.

6.2 Human Resources – Employee Hiring & Development Process

6.2.1 General

Associates performing work affecting product quality shall be competent on the basis of appropriate education, training, knowledge, skills and experience. Unless specifically excluded by management, all assemblers, warehouse clerks, electrical technicians and electronic technicians are periodically examined for visual acuity; the frequency and standards for this examination are specified in the *Matric Associate Handbook*.

6.2.2 Competence, Awareness and Training

Matric

a) Determines the necessary competence for personnel performing work affecting product quality and documents in job descriptions and career development plans. Competence is initially evaluated using information obtained from the employment application and pre-employment interview,
b) provides training or takes other actions to satisfy competency needs (Note: All associates having an impact on Ex compliance must receive appropriate training),
c) evaluates effectiveness of the actions taken through post training evaluations, a performance appraisal after a 90-day probation period and annually thereafter and through career development plans,
d) ensures personnel are aware of the quality policy, quality objectives and the implications of not conforming with QMS requirements
e) ensures that its associates are aware of the relevance and importance of their activities, ethical behaviors and how they contribute to the achievement of the quality objectives,
f) ensures personnel are aware of their contributions to product conformity and product safety 7.3
g) ensures personnel are aware of relevant QMS documented information and changes 7.3
h) Maintains appropriate records of education, training, skills and experience (see 4.2.4).

Matric procedure QOM 06-01 details the *Human Resources* process.

Matric procedure QOM 06-02 details the *Training* process.

6.3 Infrastructure

Matric has determined, provided and maintains the infrastructure needed to achieve conformity to product requirements. Matric infrastructure includes:

a) A modern facility located on 25 acres in Seneca, PA. The production section of the facility was constructed in 1995, and has been expanded to meet requirements as they arose.
Production workspace is equipped with adequate lighting, heat / air conditioning, humidification and anti-static floor coating.
The entire Matric facility is equipped with a computer network that runs the company's business and electronic communication software, as well as general office applications. This system is backed up per WI 04-02-01 Matric Systems and Data Backup Process.
b) Matric process equipment features semi-automatic through-hole printed circuit board assembly machines complemented by fully automatic surface mount process for coarse and fine pitch SMT parts, including BGAs. Inspection and test equipment includes numerous microscopes, automatic optical inspection (AOI) systems and an X-ray inspection machine. Standard electronic bench test equipment as well as automatic test equipment is available for both manufacturing defect analysis (i.e. flying probe machine) and functional test (ATE).
An Equipment List (Data 06-03-01) is available.
c) Matric depends on external providers for supporting services such as electrical power, internet access, telephone service, transportation of materials, supplies and product (incoming & outgoing) and waste disposal.
d) Matric process water and drinking water comes from an on-site well. Matric complies with all government regulations for a public drinking water system.
e) Matric operates an on-lot septic system that complies with all applicable government regulations.

Matric procedure QOM 06-03 details the procedure for *Planning New Equipment, Facilities or Processes*.

Matric uses a computer-based preventive maintenance system to minimize equipment downtime. Matric procedure QOM 07-12 *Equipment Preventive Maintenance* details preventive maintenance activities, frequencies and associated record requirements (see 4.2.4) for equipment where improper or inadequate maintenance may affect product quality.

6.4 Work Environment

Matric has determined and manages the work environment needed to achieve conformity to product requirements.

The Matric work environment includes:

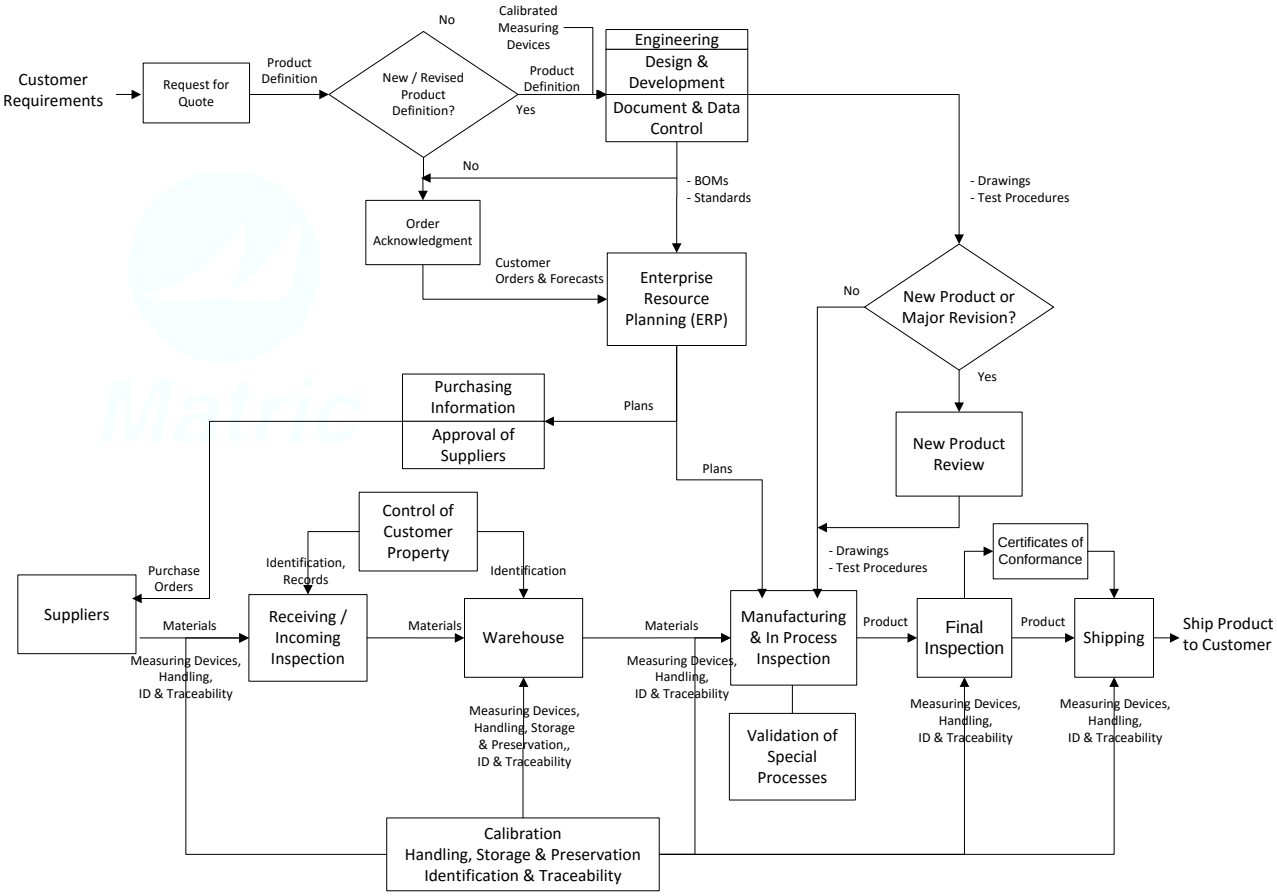
a) a strong emphasis on housekeeping. "Everything has its place and everything in its place",
b) adequate lighting, suitable for the work being performed,
c) dedicated workstations for each operation, suitable for the type of work being performed.
d) air conditioning in office and factory,
e) humidity control and monitoring in the pc board assembly and box build areas,
f) antistatic flooring with properly grounded workstations in areas where static sensitive components are handled,
g) the availability and use of anti-static devices (smocks, heel or wrist straps) by production and inspection associates,
h) designated areas for nonconforming product.
i) eating is not permitted in the production areas. Drinks and personal items are not permitted at production workstations.

Guidelines for appropriate work attire, personal hygiene, health and cleanliness are defined in the Matric associate handbook (data 06-01-01).

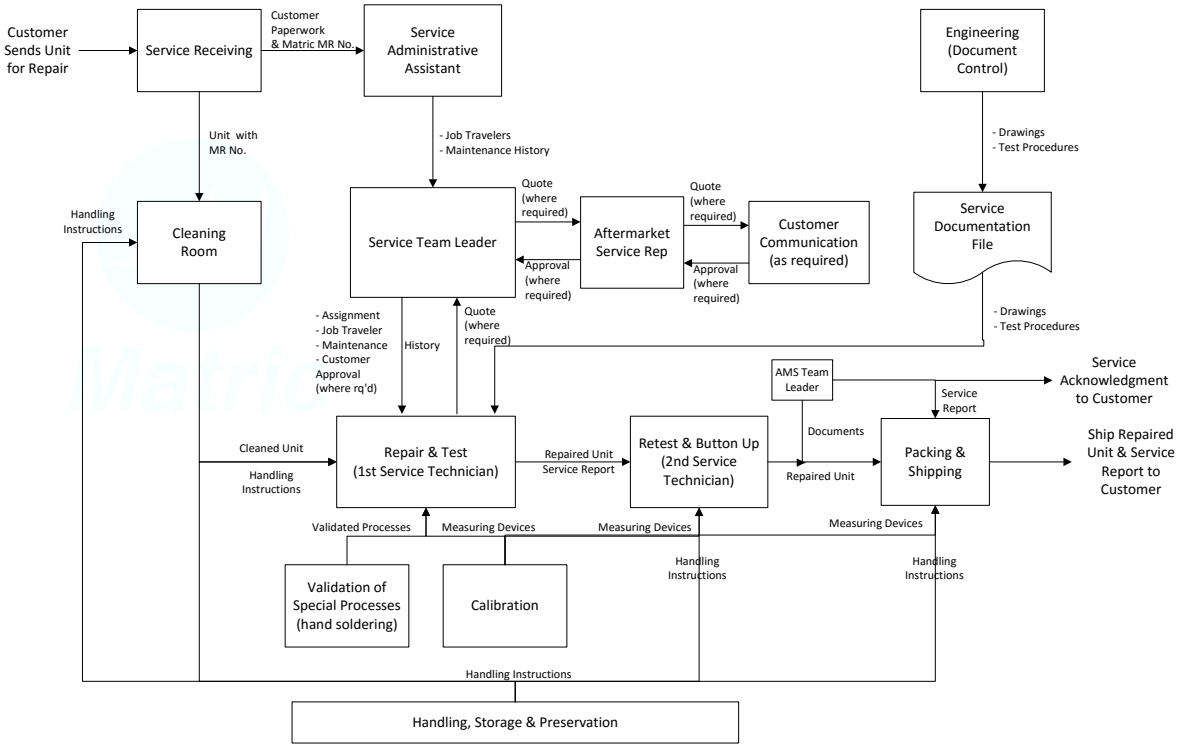
7. Product Realization

NOTE: Matric manufactures assemblies that are used in medical devices but does not manufacture registered medical devices.

Product Realization Process for New / Revised Products



Product Realization Process for Aftermarket Service



7.1 Planning of Product Realization

Matric's product realization consists of the design, manufacture / test and service / repair of cables, wire harnesses, printed circuit board assemblies and upper-level electronic products. Matric plans and develops the processes needed for these product realizations (refer to flow charts) which are detailed in quality procedures and work instructions. Planning of product realization is consistent with the requirements of the other processes of the QMS (see 4.1).

In planning product realization, Matric determines the following, as appropriate:

a) quality objectives and requirements for the product;
Quality objectives and requirements for the product include consideration of aspects such as:
- product and personal safety
- reliability, availability and maintainability
- producibility and inspectability
- suitability of parts and materials used in the product
- selection and development of embedded software
- recycling or final disposal of the product at the end of its life.

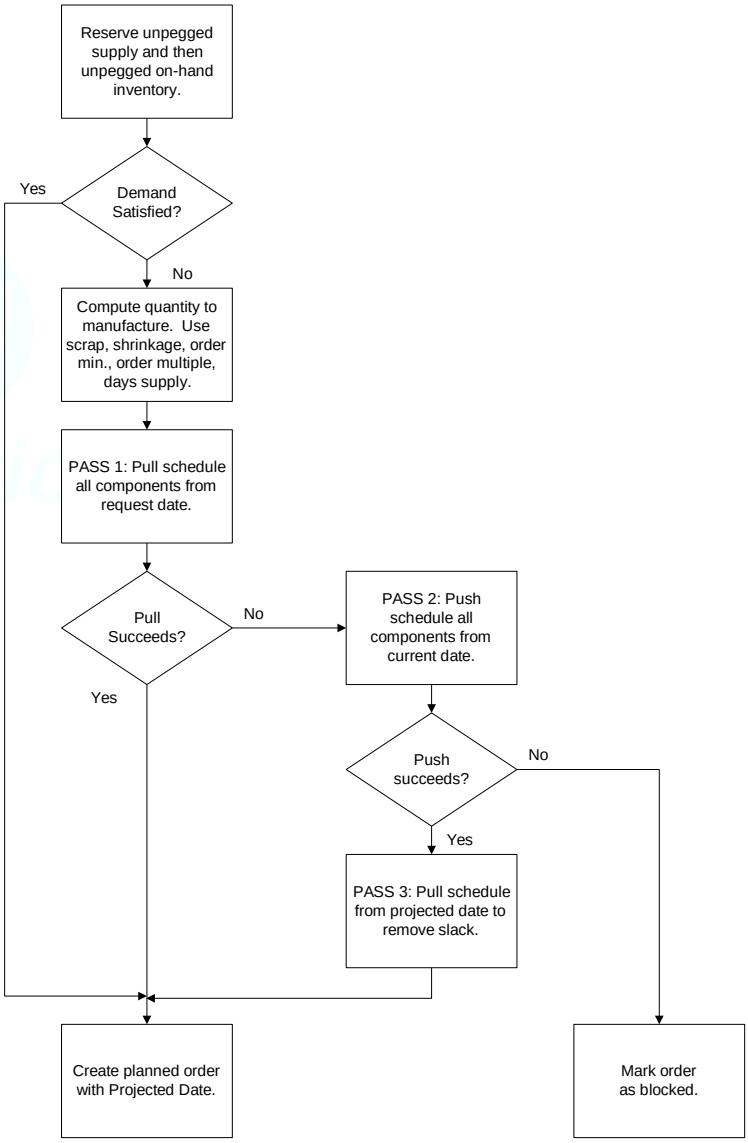
b) the need to establish and control processes, documents, and provide resources specific to the product;
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
e) Configuration management appropriate to the project.
f) Resources to support use and maintenance of the product.
g) Where a process that affects conformity with requirements is outsourced, Matric ensures control over such processes and identifies control over such processes in the QMS (see 4.1.1 and 7.4.1.4).
h) Risk is managed throughout product realization and records are maintained (See 7.1.2).

The outputs of this planning are the product drawings, labor standards, the production router and risk management records. The outputs will be suitable for Matric's operations.

Matric uses Enterprise Resource Planning (ERP) as an enterprise planning methodology. Enterprise Resource Planning is an evolution of Materials Requirements Planning (MRP II). Matric procedure QOM 07-18 details *Enterprise Resource Planning*.

Forecasts are combined with and adjusted for customer orders and fed to the ERP system. The ERP system explodes the bills of material and develops the requirements for materials. Using labor standards, the ERP system calculates labor requirements. Where capacity planning is used, the labor requirements are fed to the capacity-planning module which tests the schedule developed by ERP against current capacity. Netting of on-hand inventory balances and work in process is included as a regenerative procedure. The outputs of the MRP system are plans for ordering raw material and for manufacturing subassemblies and finished goods.

- Matric procedure QOM 07-01 details the Quality Planning Procedure for new / revised products.
- Matric utilizes a computerized Advanced Planning and Scheduling (APS) system as a tool in managing / scheduling material and production resources to identify and meet promise dates.
- APS looks at demand for each order all the way through the bill of materials. APS synchronizes production with customer orders, providing constant visibility of projected ship dates.
- The basic steps in planning production and materials with APS are:
    - Enter forecast & customer requirements with request dates.
    - Run APS daily
    - Troubleshoot production plan issues daily
    - Firm APS planned orders as late as possible
    - Schedule job orders.



APS Planning Logic

7.1.1 **Project Management**

Matric plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints. For details, reference the following applicable procedures:

- QOM 07-01 *Quality Planning*
- QOM 07-05 *Engineering Design and Development*
- QOM 07-11 *Aftermarket Service of Customer Equipment*
- QOM 07-18 *Enterprise Resource Planning*

7.1.2 Risk Management

A. QOM 07-01 *Quality Planning* defines Matric's process for managing risk to the achievement of applicable requirements, including:

a) Assignment of risk management responsibilities
b) Defines risk criteria (likelihood, consequences, risk acceptance)
c) Identification, assessment and communication of risks throughout product realization
d) Identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
e) Acceptance of risk remaining after implementation of mitigating actions.
f) Records of risk management are maintained.

B. QOM 07-20 defines Matric's risk management program for counterfeit parts.

7.1.3 Configuration Management

QOM 07-06 *Engineering Document & Data Control* defines Matric's *Configuration Management* procedure which includes, as applicable:

- Configuration management planning
- Configuration identification
- Change control
- Configuration status accounting
- Configuration audit

7.1.4 Control of Work Transfers

QOM 07-01 *Quality Planning* defines the process to plan and control the temporary or permanent transfer of work to Dynamic Manufacturing, a Matric Group company, and to verify conformity of the work to requirements.

When work performed by Matric is temporarily or permanently transferred to a supplier, the item is changed in the business computer system from "manufactured" to "purchased" and subsequently follows the standard purchasing processes. When work is transferred from one supplier to another, the transfer follows the standard purchasing processes.

The standard purchasing processes are defined in QOM 07-07 *Selection, Evaluation and Re-evaluation of Suppliers*, QOM 07-08 *Purchasing Information* and QOM 07-09 *Verification of Purchased Product*.

7.2 Customer-related Processes - Request for Quotation Process & Customer Order Entry Process

7.2.1 Determination of Requirements Related to the Product (may include "special requirements," reference AS9100)

Matric determines:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but intended for specified or intended use, when known,
c) statutory and regulatory requirements related to the product, and
d) Any additional requirements determined by the organization.

7.2.2 Review of Requirements Related to the Product

Matric reviews requirements related to the product. This contract review is conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes / amendments to contracts or orders) and ensures that

a) product requirements are defined and documented (Where the customer provides no documented statement of requirements, the customer requirements, including relevant data, e.g. product part number and revision level, shall be confirmed before acceptance),
b) contract or order requirements differing from those previously expressed are resolved (Where product requirements are changed, relevant documents are amended and relevant personnel are made aware of the changed requirements).
c) the organization has the ability to meet the defined requirements,
d) special requirements of the product are determined,
e) risks (e.g. new technology, short delivery time frame) have been identified (see 7.1.2)
f) The review shall ensure that the customer requirements are compatible with the Ex Certificate(s) (e.g. equipment group, temperature class, type of protection, EPL and ambient temperature range).

Records of the results of the review, actions arising from the contract review and any new requirements are maintained (see 4.2.4).

Matric procedure QOM 07-02 details the *Customer Order Acknowledgement Process (Including Contract Review)* for new/ revised products.

Matric procedure QOM 07-03 details the *Request for Quotation* process.

7.2.3 Customer Communication

Matric has determined and implemented 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,
d) handling and controlling customer property,
e) advisory notices - Since Matric does not sell end items, Matric does not issue advisory notices.

Matric procedure QOM 07-04 describes *Customer Communication* arrangements.

7.3 Design and Development Process

7.3.1 Design and Development Planning

Matric plans and controls the design and development of products. Interfaces between different groups involved in design and development are managed to ensure effective communication and clear assignment of responsibility.

During the design and development planning, Matric determines
a) the design and development stages,
b) the review, verification, validation and design transfer activities that are appropriate to each design and development stage,
c) the verification, validation and design transfer activities appropriate at each design and development stage,
d) the responsibilities and authorities for design and development,
e) methods for traceability between inputs and outputs,
f) the need for customer and user involvement in the process,
g) the requirements for subsequent provisions for products, and
h) the level of control expected for the process by customers and other relevant interested parties, including the competence of personnel.

The management of design and development projects includes creating and monitoring schedules consisting of tasks with assigned dates, internal and external resources and responsibilities, with design input/output data and design constraints defined as appropriate. Planning output is documented and updated as appropriate, as the design and development progresses.

- These tasks are based on safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.
- Design and development planning considers the ability to produce, inspect, test and maintain the product.

- Planning output is documented, updated and retained as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and records maintained (see 4.2.4). These inputs shall be adequate for the design and include:

a) Functional, performance, usability and safety requirements, according to the intended use,
b) applicable statutory, regulatory requirements and standards,
c) where applicable, information derived from previous similar designs, and
d) Other requirements essential for design and development of products and processes,
e) Output(s) of risk management (see 7.1) including potential consequences of failure due to the nature of the product.

Requirements must be complete, unambiguous, able to be verified or validated and not in conflict with each other. These inputs must be reviewed for adequacy and approved.

7.3.3 Design and Development Outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria,
d) specify the characteristics of the product that are essential for its safe and proper use,
e) specify, as applicable, any critical items, including key characteristics, and specific actions to be taken for these items.

Records of the design and development outputs shall be maintained (see 4.2.4). These records can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

As part of the design and quality planning process, required data is defined to allow the product to be identified, manufactured, inspected, used and maintained; this can include details for preservation of the product. For example, this may include:
- drawings, bill of materials and specifications necessary to define the configuration and design features of the product, and
- the material, process, manufacturing and assembly data needed to ensure conformity of the product.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements and achieve the intended results of the inputs,
b) to identify any problems and propose necessary actions
c) to authorize progression to the next stage.

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

Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design, the participants involved and the date of the review. (see 4.2.4).

7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.
Verification plans will be documented and include methods, acceptance criteria, and statistical techniques with rationale for samples sizes, as appropriate. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

NOTE: Matric does not design end-use medical device that would be connected to or have interface with other medical device.

7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Validation plans will be documented and include methods, acceptance criteria, and statistical techniques with rationale for samples sizes, as appropriate. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product.

Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.6.1 Design and Development Verification and Validation Testing

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

a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria,
b) test procedures describe the method of operation, the performance of the test and the recording of the results,
c) the correct configuration of the product is submitted for test,
d) the requirements of the test plan and the test procedures are observed, and
e) the acceptance criteria are met.

NOTE: Matric does not design end-use medical device and does not perform clinical evaluations.

7.3.6.2 Design and Development Verification and Validation Documentation

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

7.3.6.3 Design and Development Transfer

Procedures for the transfer of design and development outputs to manufacturing shall be documented. The procedures will ensure the outputs are verified as suitable for manufacturing before becoming final product specifications and that manufacturing capability can meet product requirements.

7.3.7 Control of Design and Development Changes

Design and development changes shall be identified, and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Design and development changes to released products shall be controlled in accordance with Matric's configuration management process.

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

The Authorized Person identified in 5.5.4 shall approve any changes that could compromise compliance with an Ex Certificate.

Matric procedure QOM 07-05 details the *Engineering Design and Development* process.

Matric procedure QOM 07-06 details the *Engineering Document Control* process including configuration management.

7.4 Purchasing Process

7.4.1 Purchasing Process

Matric ensures that purchased product and outsourced product-realization processes conform to specified purchase requirements. The type and extent of control applied to the supplier of the purchased product/outsourced product-realization process shall be dependent upon the effect of the purchased product/outsourced product-realization process on subsequent product realization and final product (see section 4.1 for additional requirements for outsourced process). Refer to QOM 07-20 for managing risk associated with counterfeit parts.

Matric accepts responsibility for conformity of all products purchased from suppliers, including product from sources defined by the customer. Matric will identify and manage the risks associated with purchased material and the suppliers selected for service.

7.4.1.1 Supplier Selection, Evaluation and Re-evaluation

Matric evaluates and selects suppliers based on their ability to supply product/outsourced product-realization processes in accordance with requirements. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.4). When available, Matric may consider supplier quality data from objective and reliable sources (information from accredited QMS or process certification bodies, organization approvals from government authorities) as one factor in supplier selection and evaluation. If such data is available and considered, Matric remains responsible for verifying that purchased product meets specified purchase requirements. Criteria for *Selection, Evaluation and Re-evaluation of Suppliers* are established and defined in Matric procedure QOM 07-07.

Suppliers providing product, process or service that can affect the product's compliance with an Ex certificate shall only be selected only after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements. Documented objective evidence that the supplier can provide a product, process or service that is fit for its purpose shall be made by one or more of the following methods:

- the supplier has an acceptable Ex quality system,
- the supplier has a quality system certificate in accordance to the appropriate standard and with an acceptable scope.
- A documented site assessment to ensure that all relevant controls are available, documented, understood and effective. The evaluation should take the following

into account: 1) criticality of the product, process or service, 2) degree of difficulty or variability in the manufacturing process, 3) location of the supplier and hence the effectiveness of communications 4) whether the supplier, in turn, sub-contracts the product, process or service.

7.4.1.2 **Acceptance Requirements for Protection Components of a Product with an Ex Certificate**

Where features affecting the type of protection of a product with an Ex Certificate cannot be verified at a later stage, then the product, process or service shall only be accepted by one of the following methods:

a) Matric can demonstrate that the control process implemented by the subcontractor ensures Ex compliance,
b) The body responsible for verification of the quality system performs periodic audits at the subcontractors,
c) suppliers not used for a period exceeding one year shall be re-evaluated prior to placing of a contract or a purchase order;
d) requirements for b) and c) are not mandatory for products, processes or services where Matric verifies conformance in accordance with 7.4.3;
e) the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year. "Review" is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers, e.g. receiving inspection report analysis.
f) Matric facilitates an arrangement whereby the body responsible for the verification of the Ex Quality System may also verify aspects of any supplier's operation that affects the type of protection.

7.4.1.3 **Supplier Management**

Matric:

a) maintains a register of its suppliers that includes approval status (e.g. approved, conditional, disapproved) and the scope of the approval (e.g. product type, process family),
b) reviews supplier performance quarterly; the results of these reviews are used as a basis for establishing the level of controls to be implemented,
c) has defined necessary actions to take when dealing with suppliers that do not meet requirements,
d) ensures that, where required, both Matric and all suppliers use customer approved special process sources,
e) defines the process, responsibilities and authority for the approval status decision, changes of approval status and conditions for a controlled use of suppliers, depending on suppliers' approval status, and
f) determines and manages the risk when selecting and using suppliers (see section 7.1.2).

7.4.1.4 Control of Outsourced Product Realization Processes (Also see 4.1.1)

For outsourced product realization processes, controls consist of these activities:

a) The supplier performing the outsourced process is evaluated and approved per 7.4.1.1. This evaluation ensures the outsourced process is performed according to the relevant current requirements of ISO 9001, AS9100, ISO 13485 and EN 80079-34.

b) In cases where it is possible to verify the outsourced process output through subsequent monitoring and measurement at Matric, no additional controls at the supplier are required. Incoming inspection and/or test at Matric shall be performed in accordance with section 7.4.3.

c) In cases where it is not possible to adequately verify the outsourced process output through subsequent monitoring and measurement at Matric, additional controls are established with the supplier. Depending on the situation, these could include certified inspection/test reports, process validation, or an agreed upon Quality Plan. In cases where additional controls are required, they shall be included in the Purchasing Information per section 7.4.2.

7.4.2 Purchasing Information

Purchasing information shall describe the product or outsourced product-realization process to be purchased, including special quality plans where appropriate:

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) QMS requirements,
d) the identification and revision status of specifications, drawings, process requirements, inspection/ verification instructions and other relevant technical data,
e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics, including those affecting conformance with an Ex Certificate,
f) requirements for test specimens (e.g. production method, number, storage condition) for design approval, inspection/verification investigation or auditing,
g) requirements regarding the need for the supplier to:
   - notify Matric of nonconforming product,
   - obtain Matric's approval for disposition of nonconforming product,
   - notify Matric of changes in product and/or process, changes of suppliers, changes of the manufacturing facility location and, where required, obtain Matric approval
   - flow down to the supply chain the applicable requirements including customer requirements,
h) record retention requirements,

i) right of access by Matric, our customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain involved in the order and to all applicable records,
j) clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the technical documentation (e.g. process control, testing or inspection),
k) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information sets out the specific quality procedures, resources and sequences of activities relevant to the particular item,
l) documents (e.g. technical specifications) stated in a particular order remain traceable to the order,
m) Matric either provides documents to suppliers with subsequent orders or has a procedure for ensuring that suppliers have current copies of documents and that their integrity is maintained.

Matric ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability given in 7.5.4.2, Matric maintains relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

Matric procedure QOM 07-08 details the *Purchasing Information* requirements, including the method by which documents (e.g. technical specifications) stated in a particular purchase order remain traceable to the order.

7.4.3 Verification of Purchased Product – Receiving Inspection Process

Matric has established and implemented incoming inspection and testing, as appropriate, for ensuring purchased product and the results of outsourced product-realization processes (where subsequent monitoring or measurement of the outsourced process is possible) meets specified purchase requirements.

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

Note 1: Matric and Matric suppliers do not use customer verification activities as evidence of effective quality control.

Note 2: Verification activities can include:
- obtaining effective evidence of the conformity of the product from the supplier (e.g. accompanying documentation, certificate of conformance, test records, statistical records, process control records),
- inspection and audit at the supplier's facility,
- review of the required documentation,
- inspection of products upon receipt,

- delegation of verification to the supplier or supplier certification.

Where purchased product is released for production use pending completion of all required verification activities, it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where Matric delegates verification activities to a supplier, the requirements for delegation are defined and a register of delegations maintained.

It is not Matric's standard practice to perform verification at the supplier's premises. If Matric or a Matric customer intends to perform verification at a supplier's premises, Matric will state the intended verification arrangements and method of product release in the purchasing information.

Requirements for purchased products affecting compliance with Ex Certificate:

a) For purchased products that can compromise the type of protection, Matric determines and implements verification arrangements which demonstrate the product's compliance with the Ex certificate, taking into account the nature of the product and the nature of the supplier.
b) When deciding what type of verification is required for a particular purchased product, Matric considers the nature of the purchased product, the supplier and how critical it is to the type of protection.
c) Where the supplier has been evaluated and documented objective evidence has been obtained to demonstrate that the supplier is fully capable of producing and verifying the product or service, no further verification of the product or service is required, provided a Declaration of Conformity according to ISO/IEC 17050-1 is supplied with each batch of product.
d) Where the Ex certificate specifies routine tests or inspections, these shall be carried out on each product. They may be carried out by the supplier or by Matric. When carried out by the supplier, this shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the supplier, e.g. by a Declaration of Conformity according to ISO/IEC 17050-1 including test results, if required.
e) Where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of encapsulated intrinsically safe circuits, then the product shall only be accepted if supplied with a Declaration of Conformity according to ISO/IEC 17050-1. This shall specifically state compliance to the purchase documents, e.g. a quality plan that lists the factors that together demonstrate conformity of the product.
f) Where sample inspections or tests are permitted, they shall be conducted in a manner which demonstrates conformity of the entire batch.
g) Where either the supplier or the manufacturer requires training or specialist skills or knowledge to carry out verification, then the training material, specialist skill, knowledge or background shall be documented, and training records maintained.

h) Where Matric chooses not to carry out inspections and tests on our own premises, then inspections and tests shall be performed on the supplier's premises under Matric's responsibility.
i) Where a supplier provides product with evidence of conformity applicable to use in an explosive atmosphere (e.g. Ex Certificate), then further verification is not required unless Matric considers it necessary.
j) Where verification of a purchased product relates to the material (metals, alloys, non-metallic parts, resins and similar), a specific Certificate of Analysis or Declaration shall be supplier.

Matric procedure QOM 07-09 details *Verification of Purchased Product* including special requirements for a purchased product or service affecting conformance to Ex Certificate.

7.5.1 Control of the Production Process and Aftermarket Service Process

Matric plans and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable

a) availability of documented information that describes characteristics of the product (drawings, parts lists, materials & process specifications, test procedures),
b) availability of documented procedures, documented requirements, work instructions, reference materials, reference measurement procedures, process flow charts, production documents (process control plans, travelers, routers, work orders) and inspection documents as necessary,
c) the use of suitable equipment (specified on production routers and service work instructions / test procedures, may include specific tools [jigs, fixtures, molds] and software programs),
d) availability and use of monitoring and measuring devices (specified on routers, test procedures and work instructions),
e) the implementation of monitoring and measurement (specified in work instructions), and
f) the implementation of final inspection/ release, labeling, packaging/packing, delivery and aftermarket service,
g) accountability for all product during production (e.g. parts quantities, split orders, nonconforming product),
h) evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
i) provision for the prevention, detection and removal of foreign objects,
j) monitoring and control of utilities (e.g. water, compressed air, electricity) and supplies (e.g. chemical products) to the extent they affect conformity to product requirements,
k) use of suitable infrastructure and environment for the operation of processes,

l) criteria for workmanship, specified in the clearest practical way (e.g. written standards, representative samples, illustrations),
m) the appointment of competent personnel and actions to prevent human error,
n) for products with Ex Certificates, Matric provides procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to compliance of the product with the type as described in the Ex Certificate.

Matric's planning considers, as appropriate:

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

Matric procedure QOM 07-10 details *Control of the Production Process*.
Matric procedure QOM 07-11 details the *Aftermarket Service of Customer Equipment*.

7.5.1.1 Production Process Verification

Matric performs first article inspection by inspecting a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results (e.g. engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to production processes are identified.

Matric controls and documents changes affecting processes, production equipment, tools or software programs. Records of changes that affect product and production processes are retained.

The results of changes to production processes are assessed to confirm the desired effect has been achieved without adverse effects to product conformity.

7.5.1.2.1 Cleanliness of Product and Contamination Control

Matric performs visual inspection to IPC-A-610 to verify process agents are removed from printed circuit board assemblies during manufacture.

Where cleanliness of a printed circuit board assembly is significant in the customer's use (e.g. very high impedance circuits), Matric will sample test for cleanliness using our ionic contamination tester.

Any other special requirements for product cleanliness are developed and implemented on an as-needed basis.

Matric does not manufacture sterile medical device assemblies or equipment.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate or control/monitor product realization processes are validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/ condition checks, are defined for production equipment and tooling in storage.

7.5.1.4 Post-Delivery Support

Matric's aftermarket service provides, as applicable, for the:

a) collection and analysis of in-service data,
b) actions to be taken, including investigation and reporting, when problems are detected after delivery including determining if the information is to be handled as a complaint,
c) control and updating of technical documentation,
d) approval, control and use of repair schemes, and
e) meeting of statutory, regulatory and customer requirements.

The nature, use and intended lifetime of products is considered during aftermarket services. Records of servicing activities are maintained (see 4.2.4). Procedures for Aftermarket Services are in QOM 08-08.

NOTE: Matric does not perform work off site, such as at a customer's facility

7.5.1.5 Installation Activities

Matric does not manufacture end-use medical device nor perform installation activities.

7.5.2 Validation of Processes for Production and Service Provision

Matric validates any processes for production and service where the resulting output cannot be verified by subsequent monitoring or measurement (e.g. "special processes"). This includes processes where deficiencies become apparent only after the product is in use or in service has been delivered. These processes include soldering, spot welding and conformal coating. See QOM 06-03 Planning of Equipment & Processes.

Validation shall demonstrate the ability of these processes to achieve planned results.

Matric has established and documented procedures for these processes including, as applicable

a) defined criteria for review and approval of the processes,
b) approval and qualification of equipment and personnel,
c) use of specific methods, procedures and acceptance criteria,
d) as appropriate, statistical techniques with rationale for sample sizes,
e) requirements for records, and
f) revalidation and criteria for revalidation,
g) approval of changes to the processes.

Matric has established a documented procedure for the validation of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications are validated prior to use. Refer to procedure QOM 07-19 *Validation of Computer Software.*

Procedures for special processes are included in procedure QOM 07-10 *Control of the Production Process*.

7.5.3 Identification and Traceability

Matric identifies the product by suitable means to ensure conformity to requirements throughout product realization.

Matric maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Matric has established appropriate controls for acceptance authority (e.g. electronic signatures, passwords).

Matric's normal traceability policy for serialized products is to provide traceability to the production lot. Matric provides traceability to the component level (component lot no.) when invoked by customer contract.

Traceability requirements can include:

- Unique identification to be maintained throughout product life,
- The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g. delivery, scrap),
- For an assembly, the ability to trace its components to the assembly, and then to the next higher assembly, and
- For a product, a sequential record of production (manufacture, assembly, inspection/verification) to be retrievable.
- Records of traceability are maintained.

During product realization, the product status is identified with respect to the monitoring and measurement requirements. The product is identified with status with respect to monitoring and measurement requirements during all stages of production, testing, final inspection, storage and repair. Traceability is required with respect to the final product and its significant parts. Traceability may be achieved using serial number, batch number or other acceptable methods.

Note: Matric does not manufacture implantable medical device.

Identification and Traceability are detailed in procedure QOM 07-13.

QOM 07-11 *Aftermarket Service of Customer Equipment* defines procedures to ensure all products returned to Matric are identified and distinguished from conforming product.

7.5.4 Customer Property

Matric exercises care with customer property, including intellectual property and personal data, while it is under Matric's control. Matric identifies, verifies, protect and safeguards 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, this will be reported to the customer and records maintained (see 4.2.4). All Matric associates are required to sign a Confidential Information Agreement upon employment. Matric signs nondisclosure agreements with customers.

Matric verifies compatibility of such customer-supplied product with the requirements of the Ex certificate.

Control of Customer Property is detailed in procedure QOM 07-14.

7.5.5 Preservation of Product – Handling & Storage of Material Process and Pack & Ship Process

Matric preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. This preservation also applies to constituent parts of a product. All chemicals must be approved before being brought into the facility.

Matric's manufactures products that Matric's customer(s) incorporate(s) into end products with Ex Certificates. Matric's customer provides instructions to the end user.

Preservation of products 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 handing for sensitive products
d) Marking and labeling including safety warnings
e) Shelf life control and stock rotation
f) Special handing for hazardous materials
g) Special storage conditions.
h) Special packaging and/or shipping containers
i) Documenting requirements for special conditions needed if packaging alone cannot provide preservation.

The *Handling, Storage and Preservation* of Product process is detailed in procedure QOM 07-15.

The *Packing and Delivery* of Product process is detailed in procedure QOM 07-16.

7.6 Control of Monitoring and Measuring Devices – Calibration Process

Matric has determined monitoring and measurement to be undertaken, and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

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

NOTE: Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce

inspection data. It also includes customer supplied equipment used to provide evidence of conformity. Matric does not permit the use of personally owned equipment to provide evidence of conformity.

Matric has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Matric ensures environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
b) be adjusted or readjusted as necessary;
c) be identified to enable the calibration status to be determined;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

Matric has established, implemented and maintains a process for recalling monitoring and measuring equipment requiring calibration or verification.

In addition, Matric assesses and records the validity of the measuring results when the equipment is found not to conform to requirements. Matric takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained (see 4.2.4).

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

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

Suppliers of calibration services (including verification on measuring devices by comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements.

Subcontractors providing calibration services shall be an accredited calibration authority, registered with a third party in accordance with an internationally recognized standard. A registration certificate bearing the accreditation logo shall be obtained and maintained on file.

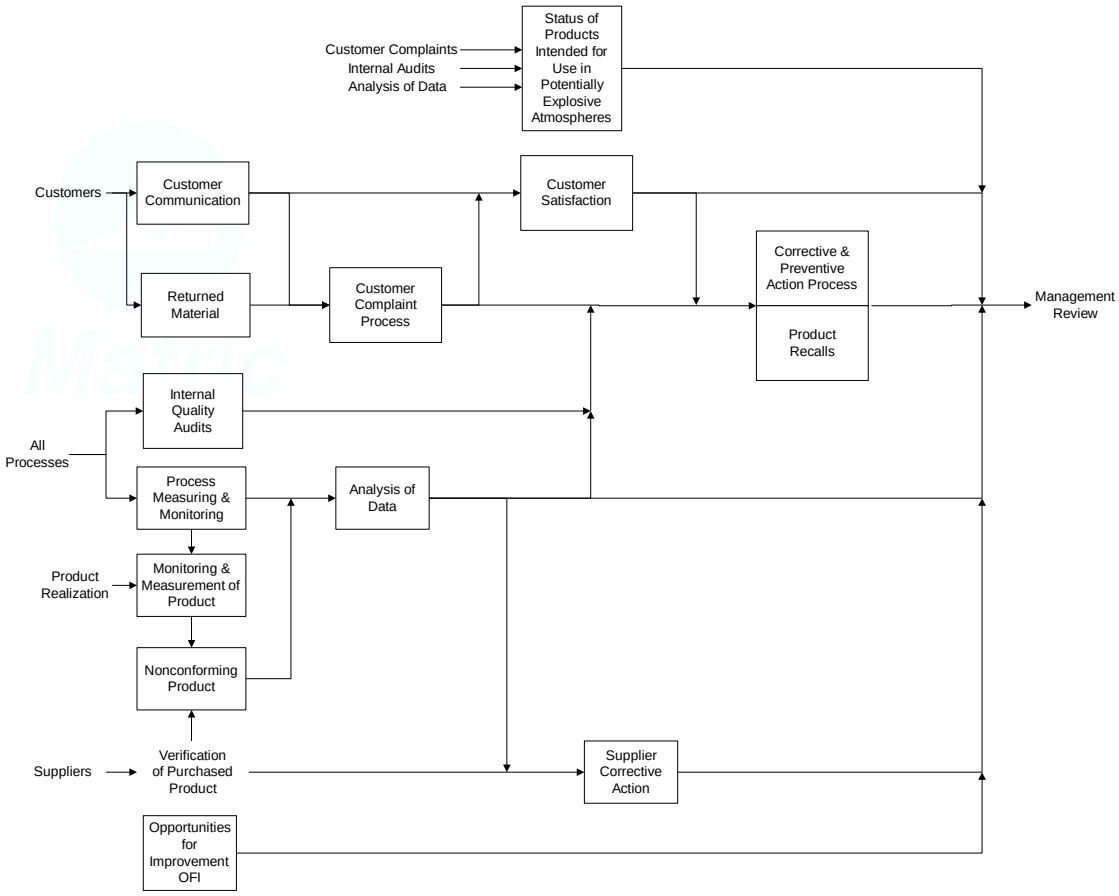
Where a calibration certificate does not bear the accreditation logo of a national accreditation authority (e.g. NADCAP, AALA), then each calibration certificate shall include at least the following information:

- an unambiguous identification of the item calibrated,
- evidence that the measurements are traceable to international or national measurement standards,
- the method of calibration
- a statement of compliance with any relevant specification,
- the calibration results,
- the uncertainty of the measurement, where necessary,
- the environmental conditions, where relevant,
- the date of the calibration,
- the signature of the person under whose authority the certificate was issued,
- the name and address of the issuing organization and the date of issue of the certificate,
- a unique identification of the calibration certificate.

Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, or does not contain the information listed in 7.6 a) of ISO 9001:2008, Matric shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).

The Calibration of *Measuring and Monitoring Devices* is detailed in procedure QOM 07-17.

8 Performance Evaluation - Measurement, Analysis and Improvement



Sequence & Interaction of Measurement, Analysis & Improvement Processes

8.1 General

Matric plans and implements the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,
b) to ensure conformity to and the effectiveness of the QMS,
c) to maintain and continually improve the effectiveness of the QMS

This includes determination of applicable methods, including statistical techniques, and extent of their use. Records of performance evaluation will be retained.

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

- design verification (reliability, maintainability, safety)

- process control
  - selection & inspection of key characteristics
  - process capability measurements
  - statistical process control
  - design of experiments
- inspection
- failure mode, effect and criticality analysis

8.2 Monitoring and Measurement

8.2.1 Customer Feedback and Satisfaction

As one of the measurements of the performance of the QMS, Matric monitors information relating to whether Matric has met customer requirements and whether the customer perceives Matric has met customer requirements. Such information is obtained by methods such as, but not limited to: customer report cards, awards, repeat business/ lost business analysis, letters, supplier certifications, measures of product conformity (customer rejections, warranty claims, customer complaints/ corrective action requests), on time delivery performance and surveys of key personnel at major customers. This information serves as input to management review meetings and potentially to the corrective action system and process improvement activity.

The monitoring of *Customer Satisfaction* is detailed in Matric procedure QOM 08-01.

NOTE: For Customer Complaint Handling – see section 8.5.2.
NOTE: Matric does not manufacture end use medical device and does report complaints or advisory notices to Regulatory Authorities.

8.2.2 Internal Audit Process

Matric conducts internal audits of the QMS at planned intervals to determine whether the quality system

a) conforms to the planned arrangements including customer contractual requirements (see 7.1), to the requirements of the ISO 9001, AS 9100, ISO 13485, EN 80079-34 and ATEX 2014/34/EC standards, and to the Matric QMS requirements

b) is effectively implemented and maintained

The audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits are planned and performed in an objective and impartial manner.

Auditors must be independent and shall not audit their own work or that of their department.

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

The internal audit program addresses the effectiveness of the elements of the quality system as described in EN 80079-34 and ATEX 2014/34/EC to ensure products are in conformity with the Ex Certificate. The maximum time between internal audits should normally be 12 months and shall not exceed 14 months.

Records of internal audits are maintained (see 4.2.4).

The *Internal Audit Process* is detailed in Matric procedure QOM 08-02.

8.2.3 Monitoring and Measurement of Processes

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

In the event of a process nonconformity, Matric:

a) takes appropriate action to correct the nonconforming process
b) evaluates whether the process nonconformity resulted in a product nonconformity
c) determines if the process nonconformity was limited to a specific case or whether it could have affected other processes or products, and
d) identifies and controls any nonconforming products (see 8.3)

Where a process can affect the integrity of a type of protection (e.g. Ex Certificate), and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored, and documentary evidence shall be maintained to demonstrate compliance with required parameters.

The responsibilities and requirements for *Process Measuring and Monit*oring are detailed in Matric procedure QOM 08-03.

8.2.4 Monitoring and Measurement of Product – Inspection & Test Process

Matric monitors and measures the characteristics of the product through inspections and tests, as appropriate, to verify product requirements have been met. These inspections

and tests are carried out at appropriate stages of the product realization process in accordance with instructions on the Matric router.

Associates performing visual inspections and making product acceptance decisions are periodically examined for visual acuity; refer to section 6.2.1.

Measurement requirements for product acceptance are documented and include:

a) criteria for acceptance and rejection
b) where in the sequence measurement and testing operations are to be performed
c) required records of the measurement results (at a minimum, acceptance or rejection)
d) any specific measurement instruments required, and any specific instructions associated with their use
e) test equipment used to perform measurement activities.

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

When Matric uses sampling inspection as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (appropriately matching the sampling plan to the criticality of the characteristic being inspected and to the process capability).

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

Where required to demonstrate product qualification, Matric ensures that records provide evidence that the product meets defined requirements. Evidence of conformity with acceptance criteria is maintained through use of an Inspection Card. This record indicates the associate who authorized release of the product for delivery to the customer (see 4.2.4).

Where routine tests are required by the Ex certificate and by the technical documentation, these tests shall be performed as specified. Unless specifically permitted by the Ex Certificate and the technical documentation, statistical methods shall not be used.

Product release shall not proceed until all operations specified on the router including final inspection have been completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. Service delivery shall not proceed until all steps in the applicable work instruction have been completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The responsibilities and requirements for *Monitoring and Measurement of Product* are detailed in Matric procedure QOM 08-04.

The responsibilities and requirements for issuing *Certifications of Conformance* and Declarations of Conformity are described in Matric procedure QOM 08-05.

8.3 Control of Nonconforming Product

Matric ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

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

Matric deals with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity (i.e. rework). When nonconforming product is corrected through rework, it shall be subject to re-verification to demonstrate conformity to requirements.

b) by authorizing its use, release, acceptance or repair under concession by the relevant design authority (includes personnel delegated authority from the design organization) and, where the nonconformity results in a departure from contractual requirements, by the customer (see QOM 08-07 *Deviations and Waivers*). Concessions for nonconforming medical device or aerospace products may be accepted only if regulatory requirements are met. Concessions for product that take the product outside the design as defined in the Ex Certificate and associated documents are not permitted. Records of the identity of the person(s) authorizing the concession are maintained (see 4.2.4). When a repair of a product is authorized, it shall be subject to verification to demonstrate conformity to the repair instructions.

c) By taking action to preclude its original intended use or application (i.e. scrap). Aerospace product dispositioned as scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. Where it is discovered that nonconforming product has been supplied to a customer, Matric will take action appropriate to the degree of risk. Matric maintains a system such that in the event of product being nonconforming (includes not complying with the Ex Certificate) and having been supplied, then the customer can be identified. Where an unsafe, nonconforming (for aerospace products, any nonconforming) product has been supplied to a customer, Matric will inform its customer in writing in a timely manner so the nonconforming items may be located and withdrawn from service;

where the product conforms to an Ex Certificate, then the body responsible for verification of the quality system and the issuer of the Ex Certificate will also be notified.

NOTE: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors, the body responsible for verification of the quality system and regulatory authorities.

e) By taking actions necessary to contain the effect of the nonconformity on other processes or products.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

For all non-conforming product conforming an Ex Certificate, Matric shall maintain, for a minimum of 10 years, records of: 1) serial numbers or identification of products supplied, the customer who received the product, the action taken to inform customers and the relevant notified body in the case of unsafe nonconforming product, 4) the action taken to implement corrective and preventive action.

For medical device products, if a product needs to be reworked (one or more times), Matric documents the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product is made and documented (see 4.2.3 and 7.5.1).

Matric's documented procedures define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions. The controls and related responsibilities and authorities for dealing with *Nonconforming Product* are detailed in Matric procedure QOM 08-06.

Matric procedure QOM 08-07 details the procedure for *Deviations and Waivers*.

Matric procedure QOM 08-08 details the procedure for *Processing of Returned Material*.

Matric procedure QOM 08-09 details the procedure for *Product Recalls*.

8.4 Analysis of Data

Matric determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information related to
a) customer feedback and level of satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) the effectiveness of planning activities,
d) performance, effectiveness and any need for improvement of the QMS,
e) characteristics and trends of processes and products, including opportunities for preventive actions and improvement,
f) the effectiveness of actions taken to address risks and opportunities,
g) suppliers,
h) audits and
i) service reports, as appropriate.

Records of this analysis are maintained (see 4.2.4).

Matric procedure QOM 08-10 details the requirements for *Analysis of Data*.

8.5 Improvement

8.5.1 Continual Improvement

Matric identifies and implements any changes necessary to ensure, maintain and improve the continued suitability, adequacy and effectiveness of the QMS using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Continual improvement opportunities can result from lessons learned, problem resolutions and the benchmarking of best practices. Significant or sustained lack of improvement must be met with corrective action.

Matric monitors the implementation of improvement activities and evaluates the effectiveness of the results.

Note: Since Matric does not design or manufacture registered medical devices, medical device advisory notices are not applicable.

Matric procedure QOM 08-11 detail's Matric's *Continual Improvement* process and evaluation of the effectiveness of results.

8.5.2 Corrective Action Process

Matric shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. Corrective actions shall be taken without undue delay.

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

complaint, relevant information is exchanged with the organizations involved (e.g. subcontractors, suppliers, customers). If a customer complaint is not followed by corrective and/or preventive action, the reason is authorized (see 5.5.1) and recorded (see 4.2.4).

Matric has a documented procedure to notify regulatory authorities of adverse events that meet specified reporting criteria of national or regional regulations.

Matric procedure QOM 08-12 details requirements for the Corrective Action process including:

a) reviewing nonconformities (including customer complaints),
b) containment and dealing with consequences of nonconformities,
c) determining the causes of nonconformities,
d) evaluating the need for action to ensure that nonconformities do not occur,
e) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2),
f) records of results of any investigation and action taken (see 4.2.4),
g) reviewing the corrective action taken and its effectiveness,
h) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
i) specific actions where timely and/or effective corrective actions are not achieved, and
j) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive Action Process

Matric shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

Matric procedure QOM 08-12 details requirements for the Preventive Action process:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of any investigations and action taken (see 4.2.4), and
e) reviewing preventive action taken and its effectiveness.

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

Quality Policy Manual Approval and Revision Record

Rev	Date	Description of Change	Approver
20	7/30/2018	Updated to include requirements of ISO 13485:2016.	RET
19	10/26/2017	Updated to include the requirements of ISO 9001:2015 and AS9100D.	RET
18	11/28/2016	Amended Quality Policy to reflect that we provide services "for electronic applications." Removed reference to company newsletter "Tradewinds". Clarified retention period for assemblies "used in" medical devices.	RET
17	03/04/2016	Added reference to QOM 07-20 Counterfeit Parts Risk Management.	RET
16	03/10/2016	Updated to reference ATEX 2014/34/EC and revised record retention requirements accordingly. Removed statement that Matric does not design medical devices. Updated organization chart. Corrected the reference to configuration management.	RET
15	10/18/2013	Updated to explicitly address ISO 13495 and AS9100 requirements. Updated from EN 13980 to EN 80079-34.	RET
14	04/15/2013	Completely revised and rewritten.	RET
13	01/06/2012	Updated to include requirements for ISO13485, highlighted interactions of process inputs and outputs	RET
12	12/2/11	Updated to include requirements for ISO13485	RET
11	7/21/2011	Reference to ISO 9001:2000 were changed to ISO 9001.	RET
10	7/31/2009	Updated to reduce redundancies between the manual and current procedures, included items required by AS9100	RET
9	1/28/2009	Changed process matrix to match the processes defined in the Management Objectives. Changed frequency of management review meetings.	RET
8	7/01/2008	Included servicing for MLS Electrosystem in the Scope and Application sections, updated Organization Chart, added vision acuity examination requirement under Human Resources and Monitoring & Measurement of Product sections, added X-Ray, AOI and flying prober under Infrastructure.	RET
7	12/27/07	Deleted building sq.ft. from 6.3 Infrastructure, and added Mgmt. Review record retention to 5.6.1	RET
6	5/23/2006	Added "rapid organizational response" to the Quality Policy	RET
5	7/6/2005	Replaced "Responsibility Matrix" in section 4.1 a with "Process Matrix." Revised organization chart in section 5.5.1. Identified processes throughout the manual. Revised the audit frequency from annual to variable, depending on the status and importance of the processes.	RET
4	4/20/2004	Added requirements for outsourced processes. Moved Preventive Maintenance from Product Realization section to Infrastructure section.	RET

Rev	Date	Description of Change	Approver
		Updated flow charts to include all processes. Clarified that humidity control applies to PC board assembly / box build production areas.	
3	2/10/2004	Changed all references of "prEN 13980" to "EN 13980". Revised Matric organization chart (section 5.5.1). Revised interval for reviewing Quality Objectives in Town Talk meetings from semi-annual to quarterly (5.5.3).	RET
2	10/01/2003	In the "Statement of Authority" section, clarified the relationship between the Quality Policy Manual and Quality Procedures / Work Instructions. Changed title of "Scope" section to "Application". Changed title of "About Matric" section to "Scope". Added paragraphs about Matric's relationship to MLS in the "Application" and "Scope" sections. Removed the terminology of "factored items". Changed references to "Service Support" to "Aftermarket Service". Annotated Manager of Aftermarket Services as an Operations Group member in the organization chart. Added reference to QOM 07-18 for ERP. Removed statement explaining why Matric does not use statistical process control. Added diagrams detailing sequence and interaction of "Management Review", "Resource Management" and "Measurement, Analysis & Improvement" processes. Revised product realization flow chart to show the interaction with support processes.	RET
1	10/14/2002	Revised section 4: Responsibility Matrix. Added reference to QOM 07-06 under section 4.2.3 Control of Documents, removed reference to Document Master List in section 4.2.5 and replaced with "handled as a document of external origin", added high-level organization chart to section 5.5.1, changed reference to special process from procedure 08-03 to QOM 07-10 in section 7.5.2, added the prefix "QOM" to all procedure numbers. Revised 4.2.5 "Use of Third Party (i.e. registrar) Logos and Certificates."	RET
0	06/06/2002	Quality Policy Manual completely rewritten and reissued for ISO 9001:2000.	RET