



QUALITY MANUAL

PIVOT-EDM, INC. (EDM)

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OUR MISSION

To seamlessly partner with customers by providing manufacturing and design of electronic and non-electronic assemblies, resulting in a steady stream of products and ideas.

OUR VISION

At Pivot-EDM, Inc. (EDM), we're about changing peoples' lives, thereby changing our community.

We start with how we do business. Corporations, Businesses, (communities) are just groups of people with shared values and purpose. We believe that the best business is done between two people, face to face, and with the shake of a hand. We want to hear about your challenges, we want to see firsthand what you deal with everyday. "Being in your shoes" is not just a saying to us, it's how we do business. We "Go to the Gemba" because we're curious and we care. We can make a difference. We're passionate about our people and just as passionate about sharing our culture and processes. Let us help. We know that none of us are good by ourselves. Our survival is based on our ability to create and sustain community.

We want you to be a part of our community.

OUR GUIDING COMPANY PRINCIPLES

Quality comes first - - To achieve customer satisfaction, the quality of our services must be our number one priority.

Customers are the focus of everything we do - - Our work must be done with our customers in mind....providing better products and services than our competition.

Continual improvement is essential to our success - - We must strive for excellence in everything we do: in our products, in their safety and value -- and in our services, our human relations, our competitiveness and our profitability.

Employee involvement is our way of life - - WE ARE A TEAM! We must treat each other with trust and respect always: telling the truth, keeping our promises, being fair, respecting the individual and encouraging intellectual curiosity.

Integrity is never compromised - - We conduct ourselves in a manner that is socially responsible and commands respect for its integrity and for its positive contributions to society. Our doors are open to men and women alike without regard to ethnic origin or personal beliefs.

COMPANY VALUES

PEOPLE - Our people are the source of our strength. They provide our corporate intelligence and determine our reputation and quality. Involvement and teamwork are our core human values.

SERVICES - The products we manufacture are the end results of our efforts, and they should be the best our customers can get. As our products are viewed, so are we viewed.

PROFITS - Are the fruits of our labors.

2.0 Access and Control

2.1 Access

This Quality Manual is maintained on the company server in Portable Document Format (PDF) in order to prevent accidental corruption. It is the responsibility of Management to ensure the policies outlined in the Quality Manual are understood and implemented through the Quality Review Board (QRB). This manual is made available to interested parties on our company's website.

2.2 Revision

In order to maintain the effectiveness of the Quality Management System (QMS), this Quality Manual is continually revised to reflect new and improved methods and procedures. The QRB approves amendments and revisions to the Quality Manual and procedures, with exception to typographical errors or general layout corrections. Each page in the Quality Manual reflects the effective date. When procedures are modified, document revision levels are adjusted accordingly.

4 Context of the Organization

4.1 Organizational Context

The Risk and Opportunity Committee (ROC) monitors external and internal issues that are relevant to EDM's purpose and strategic direction and that affect EDM's ability to achieve the intended results of the QMS. These issues are reviewed as described in section 6.1 of this manual.

4.2 Interested Parties

The ROC monitors information about interested parties and their requirements that are relevant to the QMS. These parties and requirements are reviewed as described in section 6.1 of this manual.

4.3 Scope

Pivot-EDM, Inc. (EDM) specializes in custom manufacturing of electronic assemblies and circuit boards, both through-hole and surface mount, from prototype to full turnkey. EDM Engineers provide professional circuit board layout, electronic design and development.

EDM's QMS is applicable to activities performed onsite and meets all requirements of the current revisions of ISO:9001, ISO:13485 (see EDM102 Medical Products), and ISO:80079-34 (see EDM201 "Ex" Products). EDM is committed to ensuring our customers' requirements are met, and that their satisfaction with our performance continually improves.

4.4 Overview of Processes

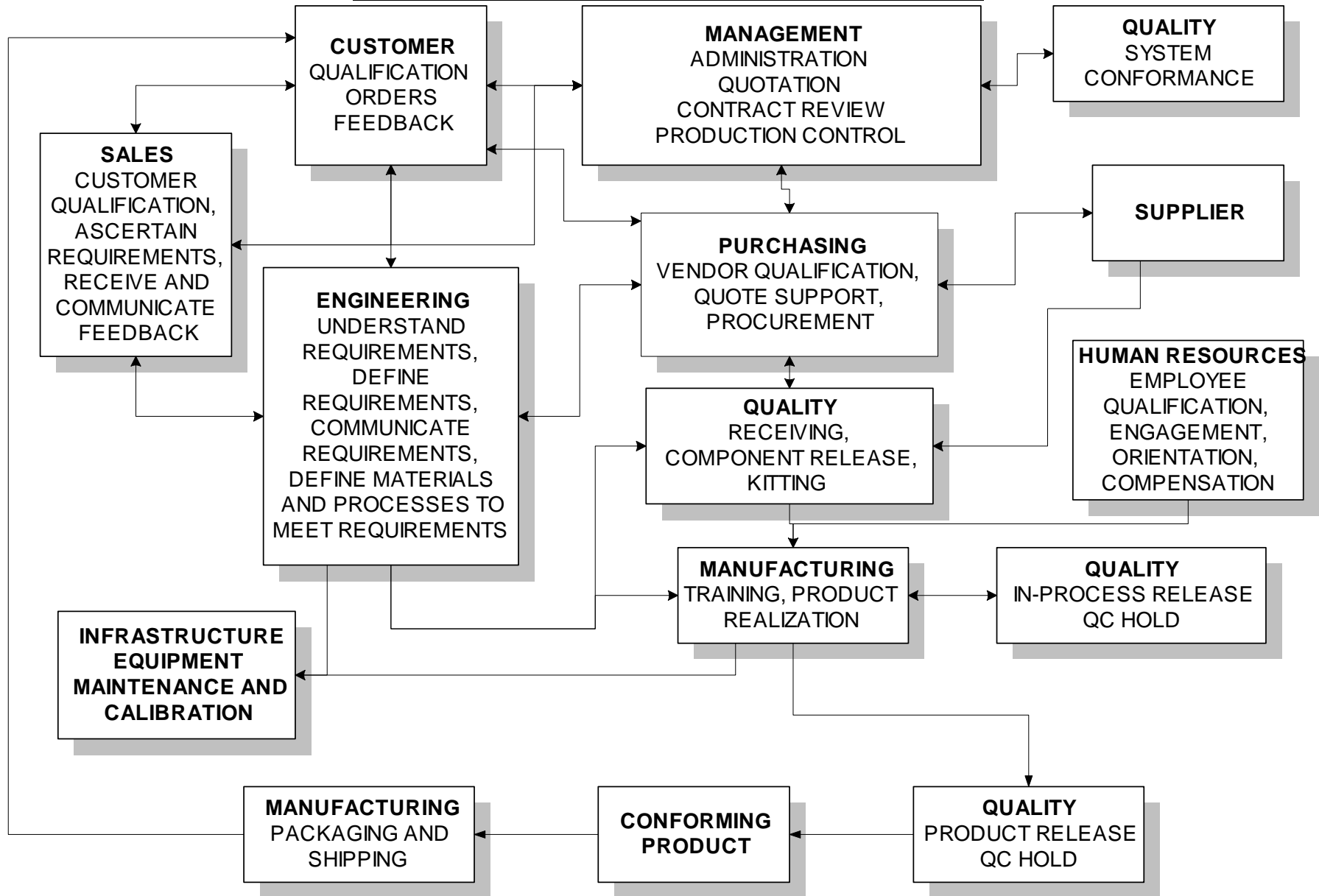
4.4.1 General

- A. EDM has designed our QMS in accordance with the requirements of the standards referenced in section 4.3 above. Processes determined to impact service provision, product quality or customer satisfaction have been identified. These are:
- Management
 - Sales
 - Human Resources
 - Engineering
 - Purchasing
 - Quality Control
 - Manufacturing
 - Infrastructure/Equipment Maintenance/Calibration
- B. The sequence and interactions of these processes are shown on page 4, as well as in Tier 2 and Tier 3 documentation.
- C. The above identified processes are analyzed, monitored, and measured where applicable. Performance is assessed against the Quality Objectives in order to ascertain that both the operation and control of these processes are effective.
- D. The availability of resources needed for QMS processes is ensured through EDM120, Management Review.
- E. The responsibilities and authorities for processes are outlined in EDM101, Management Responsibility.
- F. Risks and opportunities associated with QMS processes are identified and addressed as described in section 6.1 of this manual.
- G. Tier 2 and Tier 3 documents describe the resources required and methods used to implement the QMS, continually improve its effectiveness, meet customer requirements, enhance customer satisfaction, and achieve planned results.
- H. Continual improvement is driven by EDM employees through feedback vehicles provided for the communication of ideas and through EDM121, Internal Audit.

4.4.2 Documented Information for Processes

EDM maintains and retains documented information as detailed in section 7.5 of this manual.

FLOW CHART OF QUALITY SYSTEM



5 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top Management demonstrates leadership and commitment with respect to the QMS by:

- A. Taking accountability for the effectiveness of the QMS.
- B. Establishing and revising the quality policy and objectives, ensuring they are compatible with EDM's context and strategic direction.
- C. Ensuring that QMS processes are integrated into EDM's business processes.
- D. Promoting the process approach, risk-based thinking, and improvement.
- E. Conducting management review and ensuring the availability of resources per EDM120.
- F. Communicating the importance of conforming to an effective QMS, and ensuring the system achieves its intended results.
- G. Engaging, directing and supporting persons to contribute to the effectiveness of the QMS, including supporting the leadership of other management roles.

5.1.2 Customer Focus

Top Management ensures that the requirements of interested parties are defined and achieved, focusing on the enhancement of customer satisfaction, as further detailed in elements 6.1, 8.2.2, and 9.1.2 of this manual.

5.2 Policy

5.2.1 Quality Policy

EDM is committed to satisfying applicable requirements and to continual improvement of the Quality Management System.

5.2.2 Communication and Updates

- A. Top Management reviews the quality policy annually and communicates revisions through the use of Form 100-012, EDM Quality Objectives.
- B. The Quality Manager ensures that the quality policy is available, communicated to relevant interested parties, understood, and applied.

5.3 Responsibility and Authority

5.3.1 Responsibility and Authority

- A. The Organizational Chart Form 100-001 provides a simplified view of EDM's management structure. A flow chart showing the interaction of these functions can be found on page 4 of this manual.
- B. The responsibilities and authorities of these functions are defined throughout the QMS. These responsibilities and authorities are delegable by supervisors.
- C. Top Management ensures that the responsibilities and authorities for these roles are communicated and understood.

5.3.2 Management Representative

The Management Representative of the Quality System is the Quality Manager. The authority and responsibility of this role includes:

- A. Ensuring needed QMS processes are established, implemented, maintained, and delivering their intended outputs,
- B. Reporting QMS performance and improvement needs to Top Management,
- C. Ensuring the promotion of customer focus throughout the organization, and
- D. Ensuring the integrity of the QMS is maintained when changes are planned and implemented.

6 Planning for the Quality Management System

6.1 Risks and Opportunities

- A.** The Risk and Opportunity Committee (ROC) is appointed by Top Management and meets approximately once per month. The ROC reviews, updates, and considers the information detailed in sections 4.1 and 4.2 of this manual when determining the risks and opportunities that need to be addressed to:
- Ensure that the QMS can achieve its intended results,
 - Enhance desirable effects,
 - Prevent, or reduce, undesired effects, and
 - Achieve improvement.
- B.** The ROC plans actions, considering the potential impact on the conformity of products and services, to address these opportunities and risks. These actions include integration and implementation of activities into QMS processes when appropriate. The ROC evaluates the effectiveness of actions taken.
- C.** The Risks and Opportunities module is used to organize activities and relevant documented information.

6.2 Quality Objectives

Measurable quality objectives are established by Top Management and communicated through the use of Form 100-012. These goals, when achieved, lead to the realization of the Quality Policy. These objectives take into account applicable requirements and are relevant to conformity of products and services, as well as the enhancement of customer satisfaction.

6.3 Planning of Changes

- A.** The Quality Manager is responsible for planning changes to the QMS as detailed in section 5.3.2 of this manual.
- B.** The Quality Manager considers the purpose and potential consequences of changes, including their impacts upon the availability of resources and the allocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

- A. The EDM Management team determines and facilitates resource allocation in order to implement, maintain and continually improve the Quality Management System. This allocation focuses on meeting customer requirements in order to enhance customer satisfaction.
- B. The team considers the capabilities and constraints on internal resources, as well as what needs to be obtained from external providers, when making these determinations.

7.1.2 People

Top Management determines and provides the persons necessary for the effective implementation of the QMS as well as operation and control of processes.

7.1.3 Infrastructure

- A. Top Management has determined, provided, and maintains infrastructure for the operation of processes which result in conforming products and services. Infrastructure is maintained as defined in EDM122, Equipment Maintenance and Calibration.
- B. In the event that infrastructure is compromised, EDM231, Crisis Management Plan, is implemented as necessary.

7.1.4 Environment for the Operation of Processes

- A. EDM maintains a safety program led by the Safety and Health Manager and the Safety Committee per EDM210. The preservation of employee health is the primary concern of EDM with respect to the work environment.
- B. Additional employee requirements are addressed as specified in section 4.2 of this manual.
- C. EDM is also concerned with the effects that the work environment may have on the quality of products delivered to customers and the efficiency of manufacturing processes. For this reason, certain environmental parameters are monitored. See Environmental Monitoring and Control, EDM125, for further detail.

7.1.5 Monitoring and Measuring Resources

Monitoring and measuring resources used to verify the conformity of products and services are determined, provided, identified, and maintained as defined in EDM122, Equipment Maintenance and Calibration.

7.1.6 Organizational Knowledge

Knowledge necessary for the operation of processes is determined, maintained and made available as necessary to achieve conformity of products and services. Refer to EDM110, Manufacturing Layout and the Change Management module for specific examples of how this knowledge is gathered and made available.

7.2 Competence

Personnel performing tasks which have an impact on QMS performance, including product or service quality, are determined to be competent based on their education, training, experience and/or skills. Necessary competencies are defined, developed, and recorded as specified in EDM112, Training Requirements.

7.3 Awareness

The Quality Manager ensures that personnel are aware of the Quality Policy, the relevance and importance of their activities, how they contribute to the achievement of the Quality Objectives, the benefits of improved QMS performance, and the implications of not conforming to QMS requirements.

7.4 Communication

- A.** EDM120, Management Review, defines appropriate internal communication processes, including communication relevant to the effectiveness of the QMS.
- B.** The responsible parties and subjects of additional communication, including external communication, are defined throughout QMS procedures, delegated by supervisors, or determined in management review meetings. The specific means and timing of communication are assigned when necessary.

7.5 Documented Information

Quality Manual

- A.** The EDM Quality Manual is based on ISO 9001 (latest revision) Quality Management Standards.
- B.** The Quality Manual defines the scope of the QMS, sets forth the Quality Policy and provides an overview of operational procedures with references to the more detailed information contained in Tier 2, Tier 3 and Tier 4 documentation.
- C.** Top Management appoints members of the QRB and provides evidence of its commitment to the development and implementation of the Quality Manual.
- D.** The Manual is maintained and issued by the QRB.
- E.** Manuals distributed outside of EDM are not subject to document control.

7.5.1 General

- A.** EDM, via the QRB, ensures that the QMS is documented to achieve consistent, effective operation and control of processes. This documentation is written to provide:
 - Official declaration of the quality policy.
 - Evidence of our commitment to quality and the means used to attain it.
 - References to the policies, procedures, and general guidelines used by departments in pursuit of quality objectives.

7.5.1 General Documented Information (Continued)

- B.** QMS documentation at EDM is designed to meet the requirements of ISO 9001 (latest revision). A documentation tier structure has been adopted by EDM. This tier structure consists of the following levels:
- Tier 1: EDM Quality Manual
 - Tier 2: QMS Procedures / ERP System Tools
 - Tier 3: Work instructions
 - Tier 4: Required forms
- C.** The QMS is documented by the QRB in the EDM Quality Manual (Tier 1).
- D.** Operational procedures have been incorporated into a series of Tier 2 documents called “EDM Quality Procedures.” These documents are developed and managed by the QRB to provide for operational consistency and to meet customer requirements. These documents define the basic responsibilities and authorities of relevant functions as well as required interactions among various processes.
- E.** The ERP System has functions integrated within it to help ensure that processes are performed in a systematic manner. These systematized functions are process controls, and therefore are also maintained documented information.
- F.** Tier 3 documents provide instructions regarding practices and procedures utilized throughout the organization. Documents included in this tier are:
- Manufacturing Layouts,
 - EDM Work Instructions (EWIXXX),
 - EDM Supplier Requirements (ESRXXX), and
 - EDM Training Instructions (ETIXXX).
- G.** Tier 4 documents are forms used for data analysis for decision making, to create records or to communicate controlled information. Information stored as records within the ERP system is retained documented information as well.

7.5.2 Creating and Updating

Documented information is created, updated, identified, formatted, reviewed, and approved as defined throughout QMS processes; especially EDM103 Control of Documents and EDM111 Retained Documentation.

7.5.3 Control of Documented Information

Document Control procedures EDM103 and EDM111 provide the instructions necessary for the control of Tier 1, Tier 2, Tier 3, and Tier 4 documents.

8 Operation

8.1 Operational Planning and Control

8.1.1 Manufacturing Layout

Processes needed for product realization are planned and developed per EDM110, Manufacturing Layout.

- A. The Manufacturing Layout identifies and specifies procedures in production which directly affect the quality of customers' products.
- B. Manufacturing Layouts define production, test, monitoring, verification, release and preservation processes.
- C. The Shop Quality Control Supervisor, Plant Manager, Production Engineer and Shop Supervisor are responsible for ensuring that the applicable manufacturing procedures are carried out under controlled conditions.
- D. Quality Control plans, as documented in the Manufacturing Layouts, include detailed instructions for inspections and tests to be carried out by, or under the supervision of, the Shop Quality Control Supervisor.
- E. Resources specific to the product are specified in the Manufacturing Layout when applicable.
- F. Additional considerations related to operational planning and control are addressed elsewhere in this manual:
 - 6.0 – Planning
 - 8.5.6 – Control of Changes
 - 8.4 – Control of Externally Provided Processes, Products, and Services

8.2 Requirements for Products and Services

8.2.1 Customer Communication

- A. Communication with customers involving information relevant to products and services is accomplished as described in section 7.4 of this manual.
- B. Production Control handles enquires, contracts, orders, and order changes.
- C. Additional feedback relating to products and services is obtained as described in section 9.1.2 of this manual.

8.2.1 Customer Communication (Continued)

- D.** Top Management communicates with customers regarding the control and handling of their property. This communication is delegated to other departments as appropriate.
- E.** Top Management establishes specific requirements for contingency actions when relevant.

8.2.2 Determining the Requirements for Products and Services

- A.** Quotations are developed in order to provide customers with information related to lead time, price, and methods to be used in the manufacture of a product or provision of a service.
- B.** The following determinations are made during the quotation process (as applicable):
 - The requirements for the product or service.
 - Statutory and regulatory requirements.
 - Any additional requirements as considered necessary internally.
 - Resources are available in order to meet the claims for the offered product or service.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 Customer Sales Order Review

- A.** Each customer's purchase order, contract, or change request is reviewed before acceptance to ensure that EDM has the capability to meet their requirements. This review includes the following:
 - Requirements specified by the customer, including delivery and post-delivery activities.
 - Requirements not specified by the customer but necessary for the specified or intended use, where known.
 - Requirements specified internally.
 - Applicable statutory and regulatory requirements.
 - Contract or order requirements differing from those previously expressed.

8.2.3.1 Customer Sales Order Review (Continued)

- B.** Contract or order requirements differing from those previously expressed are resolved before order acceptance.
- C.** In the event that the customer does not provide a documented statement of their requirements, Production Control confirms customer requirements before order or contract acceptance.

8.2.3.2 Applicable Documented Information

- A.** Customer sales order and change information is entered into the ERP system in order to manage communication and maintain records.
- B.** Records of the results of the review are documented in the ERP system. Internal and external parties are informed of the results of the review when applicable. This includes acceptance or rejection as well as communication of changes.

8.2.4 Changes to Requirements for Products and Services

When requirements for products and services are changed, a Change Management record is initiated in the ERP system when applicable to ensure that related documented information is amended and that relevant personnel are made aware of the changed requirements.

8.3 Design and Development of Products and Services

- A.** Design and development activities are performed as recorded and managed in the EDMQMS database.
- B.** Top Management and Engineering collaborate to manage interfaces between interested parties, ensuring effective communication and clear assignment of responsibility.
- C.** In some instances design validation cannot be performed by EDM and is the sole responsibility of the customer.

8.4 Externally Provided Products and Services

8.4.1 General

- A.** Externally provided processes, products, and services are verified as conforming to the requirements defined by customers. The extent and type of control applied to external providers is dependent upon the effect of the purchased products on subsequent product realization.
- B.** Purchasing is responsible for evaluating and selecting suppliers based on their ability to meet quality, shipping, and pricing requirements.
- C.** The top twenty suppliers in terms of sales volume are reevaluated as an input to management review. Records of necessary actions arising from this reevaluation are retained per EDM120, Management Review.

8.4.2 Type and Extent of Control

The methods used to ensure that externally provided processes, products, and services do not adversely affect the ability to deliver conforming products and services to customers are outlined in EDM108, Receiving Inspection.

- A.** Receiving inspection verifies that externally provided processes have been performed in accordance with requirements.
- B.** The effectiveness of the controls of external providers and impact upon the ability to meet customer, statutory, and regulatory requirements have been considered in the development of the receiving inspection process.

8.4.3 Information for External Providers

Purchasing verifies the adequacy of requirements before communicating them to external providers. Purchasing communicates requirements for the following as applicable:

- The process, products, and services to be provided.
- The approval of products and services, methods, processes, and equipment, and the release of products and services.
- Any required qualification of persons.
- Communication and interactions.
- Control and monitoring of the external provider's performance.
- Verification or validation activities to be performed at the external provider's premises.

8.4.3 Information for External Providers (Continued)

- A.** Engineering approval is obtained for the initial purchase of solder stencils and printed circuit boards.
- B.** Purchasing provides EDM Supplier Requirement (ESRXXX) documented information to external providers when appropriate.
- C.** Purchase Orders are developed which clearly describe the product ordered and the requirement for a Certificate of Conformance.
 - Purchasing verifies that external providers receive purchase orders.
 - Purchase orders for the following include these statements (or similar):
 1. Calibration services: “Calibrate to manufacturer’s specifications; all ranges, all functionality, NIST traceable.”
 2. Printed circuit boards: “Fabrication, testing, documentation and packaging must conform to ESR001.”
 3. Solder paste stencils: “Files are squeegee side up; mask the mounting holes and fiducials; partially etched, dark epoxy filled.”

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Production and service provision are implemented under the following controlled conditions, as applicable:

- A.** Documented information defining the characteristics of the products and services, along with the results to be achieved, is generated and made available as detailed in EDM110, Manufacturing Layout (ML).
- B.** The ML defines the monitoring and measuring resources to be used. Resource availability is addressed as necessary per EDM120, Management Review.
- C.** The ML specifies the stages where monitoring and measurement activities take place in order to verify that criteria for the control of processes, process outputs, and acceptance of products and services have been met.
- D.** The infrastructure and environment for the operation of processes is ensured to be suitable as detailed in section 7.1.4 of this manual.

8.5.1 Control of Production and Service Provision (Continued)

- E.** Shop supervision ensures that competent and qualified people are appointed to processes.
- F.** Special Processes
 - These are processes, (such as ESD mitigation) the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met.
 - Records are maintained to monitor the continuing effectiveness of special processes as appropriate.
- G.** Shop supervision implements actions to prevent human error.
- H.** Product Release Activities are performed by or under the direction of the Shop QA Supervisor in accordance with quality plans expressed in Manufacturing Layouts. EDM116, Handling Nonconforming Outputs, is followed in the event that a nonconformance is found during inspection.
- I.** Manufacturing, assembly and servicing activities are controlled according to instructions expressed in the Production Schedule, Manufacturing Layouts, and Temporary Deviations.

8.5.2 Identification and Traceability

- A.** Packaging and marking procedures are developed per applicable requirements to identify and protect products.
- B.** The status of outputs with respect to monitoring and measurement requirements is identified within the ERP system. The location of outputs further refines their status.
- C.** When applicable, unique product identification is defined per EDM110, Manufacturing Layout. The documented information necessary to enable traceability is retained within the ERP system.

8.5.3 Property Belonging to Customers or External Providers

- A.** Property owned by customers or external providers which is furnished to EDM for the fulfillment of contractual obligations is identified, verified, protected, and safeguarded.
- B.** In the event that this property is lost, damaged, or otherwise found to be unsuitable, the owner of the property is informed. Documented information on what has occurred is retained.

8.5.4 Preservation of Product

Products are preserved and protected during internal processing by means of ESD Handling Procedures, monitoring and measurement of environmental conditions relative to manufacturing processes, observance of moisture control procedures and specific handling procedures defined per EDM110, Manufacturing Layout, to identify and maintain the conformity of components and assemblies.

8.5.5 Post-Delivery Activities

- A.** Requirements for post-delivery activities are determined during the quotation process. These are defined on the quotation and communicated to the customer. The following are considered in the development of the quotation:
 - Statutory and regulatory requirements.
 - The potential undesired consequences associated with the product or service.
 - The nature, use, and intended lifetime of the product or service.
 - Customer requirements.
 - Customer feedback.
- B.** Processing of Customer Returns
 - When a customer requests authorization to return product, the Quality Manager or Shop Quality Control Supervisor issues a Return Material Authorization (RMA) number.
 - When applicable, Engineering or Quality develops instructions for disposition of the returned product and Production Control schedules the repair for the shop.
 - When the processing of returned material is complete, relevant documented information is retained within the original ERP system sales order record and/or the Customer Satisfaction module.

8.5.6 Control of Changes

Changes, including unintended changes, are reviewed and controlled as necessary to ensure continuing conformity with requirements. Documented information describing the results of the review, the person authorizing the change, and necessary actions are retained within the Change Management module of the ERP system.

8.6 Release of Products and Services

The Quality department determines when all applicable manufacturing requirements have been met and completes the appropriate transaction in the ERP system. Materials cannot be shipped in the ERP system, and are therefore not released, until this transaction is performed. Evidence of conformity and to the person authorizing the release is retained within the ERP system.

8.7 Control of Nonconforming Outputs

Production outputs that do not conform to requirements are identified and controlled as detailed in EDM116, Handling Nonconforming Outputs. Other nonconforming outputs are identified and controlled by processing orders in the ERP system.

9 Performance Evaluation

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Quality performance and the effectiveness of the QMS are continually evaluated. Monitoring and measuring are performed as described throughout QMS processes. EDM120, Management Review, describes in further detail the subjects, methods, and timing of performance of monitoring and measurement activities. The results from monitoring and measurement are analyzed, evaluated, and have documented information retained as outlined in this procedure.

9.1.2 Customer Satisfaction

Customer satisfaction information is reviewed as described in EDM120, Management Review. The methods used to gather this information include:

- Customer feedback
- Customer complaints
- Customer Surveys

9.1.3 Analysis and Evaluation

Data and information arising from monitoring, measurement, and other sources is analyzed and evaluated according to EDM120, Management Review.

9.2 Internal Audit

- A. Internal Audits are conducted at planned intervals following EDM121, Internal Audits, to ensure the QMS is effectively implemented and maintained.
- B. Internal Audits provide information used to verify that the QMS conforms to ISO 9001 standards (current revision) as well as the QMS requirements specified internally.
- C. Internal Audits are performed by an external provider when company resources are not available.

9.3 Management Review

- A. Management Review is performed as defined in Management Review, EDM120, to ensure the continuing suitability, adequacy, and effectiveness of the Quality Management System, including its alignment with EDM's strategic direction.
- B. Top Management assesses opportunities for improvement and the need for changes to the Quality Policy and Quality Objectives on an annual basis.

10 Improvement

10.1 General

Opportunities for improvement are determined and selected for implementation. Necessary actions are undertaken in order to meet customer requirements and enhance customer satisfaction, including:

- Improving products and services to meet requirements and address future needs and expectations.
- Correcting, preventing, or reducing undesired effects.
- Improving the performance and effectiveness of the QMS.

10.2 Nonconformity and Corrective Action

Nonconformities, including those arising from complaints, are addressed as detailed in EDM124, Corrective Action.

10.3 Continual Improvement

The suitability, adequacy, and effectiveness of the QMS is continually improved. The results of analysis and evaluation, as well as the outputs from management review, are used to identify and address continual improvement needs and opportunities.