QUALITY MANUAL

ISO 9001

Quality Management System

Revision History

Date	Change Notice	Change Description
4/17/14	""	Original Release.
08/16/2017	B	Updated to Align with ISO 9001:2015

Approvals:

Nancy Rohlfs

Owner

Contents

Introduction

East Coast Precision Manufacturing, LLC was founded by Mark Rohlfs and his sister, Nancy Rohlfs. Both Mark and Nancy wanted to start a business that would be different from a typical job shop. "I have tremendous respect for job shops out there," says Mark, "but I envisioned carving out a niche in the production of precision-machined plastic parts with an emphasis on quality throughout the whole process: handling questions, quoting, production and timeliness. There's usually a breakdown somewhere in the process which makes overall quality very hard or even impossible to find."

Mark has over 20 years' experience in the plastic machining business on the production side, while Nancy has worked in senior financial and customer-service positions in both manufacturing and Fortune 500 corporate environments. Each partner has developed an area of expertise relating to the precision machined plastic component industry—enabling them to establish a business that would truly serve the customer's needs.

Mark, Nancy and their small group of machining associates work with each customer personally to understand their specific needs and to provide the most cost-effective solutions to their machining requirements. Nancy Rohlfs understands commitment to customer service. "We've all been frustrated by contacting customer service centers that are thousands of miles away from the original manufacturer or distributor of a product," she says. "It seems as if they don't understand our question or problem and don't own responsibility for fixing it." When you contact East Coast Precision Manufacturing, she points out, you speak directly with someone who can help you. "We all answer our own phones and return calls quickly," she says. "We own our machining process and will work with our customer to achieve our customer's goals."

Mark Rohlfs offers the following insights on East Coast Precision Manufacturing's company mission:

We distinguish ourselves from the typical machine shop by emphasizing a clean environment with new machines. Our attention to detail, from the shop floor to our business office, supports our goal of always meeting our customer's needs—and exceeding their expectations, whenever possible. The best way to do this is to consistently produce parts that are dimensionally and functionally correct while maintaining an appropriate cost and delivery.

We will provide samples, first piece articles and test pieces to determine which plastic machining technique fulfills the customer's needs. We believe that the customer determines the direction of our business and we work within that framework to produce the lowest overall cost with the highest quality.

With over 20 years of experience machining and finishing plastics—and a three-generation family history dedicated to precision machining—East Coast can provide the very best solution to your most challenging and difficult-to-machine parts.

We machine all types of plastics, and will support you throughout the quoting and machining process. We have experience machining manifolds, valve bodies, complex housings, cams, pressure sensor devices, insulators, bushings and many other plastic components large and small. We also provide finishing services, such as chemical and mechanical polishing, stress relief and secondary machining and finishing of molded components. We currently support many industries, such as telecommunications, industrial, medical and other high-tech industries.

Our approach is direct and personal, and we will work with you to help keep your cost within your budget. If you need to touch base with us during production, you will speak directly with the engineer/machinist producing your part. We value our customers and are committed to meeting their expectations for their machined plastic part.

Our commitment to fabricating high quality plastic components for our customers is our number- one priority.

"As a business owner, consumer and father of three small children," says Mark Rohlfs, "I notice quality in so many items I buy for my family, for myself and for my business." Interestingly, he notes, there is an increasingly wide range of quality in many of the products he sees. "My wife and I recently received 5 rubber duckies as gifts

for our son," he explains. As it turned out, two of the ducks actually worked like they were supposed to," he says. "The other three flipped over and would only float upside-down."

Mark thought about the disconnect that existed somewhere in the manufacturing process. "Somebody, someplace failed to pay attention to the details and produced a rubber ducky that would only float upside-down," he observes. "It is my intention to pay attention to the details and keep East Coast Precision Manufacturing dedicated to making all of our parts, large and small, do exactly what they are supposed to do. Because a child's toy, a device for industry or a large and complex piece of machinery all depend on components performing to their exact specifications—and we all understand just how important that is."

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This Quality Manual specifies requirements that East Coast Precision Manufacturing (ECPM) uses to address client satisfaction, to meet client and applicable regulatory and statutory requirements and to meet ISO 9001:2015 requirements, and is supported by additional procedures where necessary. The quality management principles stated in ISO 9000, and ISO 9004, have been taken into consideration during the development of this Policy Manual.

This Manual specifies the general requirements for ECPM competence towards a management system for quality, administrative and technical operations.

1   Scope

1.1   General

This Quality Manual specifies requirements for a quality management system where ECPM:

    a)   Needs to demonstrate its ability to consistently provide product and services that meet customer and applicable statutory and regulatory requirements, and

    b)   Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

2   Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems – Requirements

3   Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

4   Context of the Organization

4.1   Understanding the Organization and its Context

ECPM has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. (*See P-006*)

ECPM monitors and reviews information about these external and internal issues.

4.2   Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on ECPM's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, ECPM determined:

   a)   The interested parties that relevant to the quality management system;

   b)   The requirements of these interested parties that are relevant to the quality management system.

ECPM monitors and reviews the information about these interested parties and their relevant requirements.

4.3   Determining the Scope of the Quality Management System

ECPM has determined the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, ECPM considered:

   a)   The external and internal issues referred to in 4.1;

   b)   The requirements of relevant interested parties referred to in 4.2;

   c)   The products and services of ECPM

ECPM applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of ECPM's quality management system is available and maintained as documented information. The scope states the types of products and services covered, and provides justification for any requirements that ECPM has determined is not applicable to the scope of its quality management system.

Conformity to ISO 9001 are only claimed if the requirements determined as not being applicable do not affect ECPM's ability to ensure the conformity of its product and services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with ECPM activities and registration is:

Machining, fabrication, polishing of plastics for a variety of industries.

4.4   Quality Management System and its Processes

4.4.1   ECPM has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

ECPM has determined the processes needed for the quality management system and their application throughout ECPM, and

    a)   Determined the inputs required and the outputs expected from these processes;

    b)   Determined the sequence and interaction of these processes;

    c)   Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

    d)   Determined the resources needed for these processes and ensure their availability;

    e)   Assigns the responsibilities and authorities for these processes;

    f)   Addresses the risks and opportunities as determined in accordance with the requirements of 6.1;

    g)   Evaluates these processes and implement any changes needed to ensure that these processes achieve their intended results.

    h)   Improves the processes and the quality management system.

4.4.2   To the extent necessary, ECPM:

    a)   Maintains documented information to support the operation of its processes (See procedure list);

    b)   Retain documented information to have confidence that the processes are being carried out as planned (See Records Table).

5   Leadership

5.1   Leadership and Commitment

5.1.1   General

Top management demonstrates leadership and commitment with respect to the quality management system by:

    a)   Taking accountability for the effectiveness of the quality management system;

    b)   Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of ECPM;

    c)   Ensuring the integration of the quality management system requirements into ECPM's business process;

    d)   Promoting the use of the process approach and risk-based thinking;

    e)   Ensuring that the resources needed for the quality management system are available;

    f)   Communicating the importance of effective quality management and of conforming to the quality management system requirements;

    g)   Ensuring that the quality management system achieves its intended results;

    h)   Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

    i)   Promoting improvement; and

    j)   Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2   Customer Focus

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

    a)   Customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

    b)   The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; and

    c)   The focus on enhancing customer satisfaction is maintained.

5.2   Policy

5.2.1   Developing the Quality Policy

Top management has established, implemented and maintains a quality policy that:

    a)   Is appropriate to the purpose and context of ECPM and supports its strategic direction;

    b)   Provides a framework for setting quality objectives;

    c)   Includes a commitment to satisfy applicable requirements; and

    d)   Includes a commitment to continual improvement of the quality management system.

5.2.2   Communicating the Quality Policy

The Quality Policy:

    a)   is available and maintained as documented information;

    b)   is communicated, understood and applied within the organization; and

    c)   is available to relevant interested parties, as appropriate.

Quality Policy:

"Company-wide commitment to excellence and customer satisfaction through effective, compliant quality management and continuous improvement."

5.3   Organizational Roles, Responsibilities, and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within ECPM.

Top management assigns the responsibility and authority for:

    a)   Ensuring that the quality management system conforms to the requirements of this International Standard;

    b)   Ensuring that the processes are delivering their intended outputs;

    c)   Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

    d)   Ensuring the promotion of customer focus throughout ECPM; and

    e)   Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6   Planning

6.1   Actions to Address Risks and Opportunities

6.1.1   When planning for the quality management system, ECPM considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:

   a)   Give assurance that the quality management system can achieve its intended results;

   b)   Enhance desirable effects;

   c)   Prevent, or reduce, undesired effects; and

   d)   Achieve improvement.

6.1.2   ECPM plans:

   a)   Actions to address these risks and opportunities;

   b)   How to:

        1.   Integrate and implement the actions into its quality management system processes (See 4.4)

        2.   Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

6.2   Quality Objectives and Planning to Achieve Them

6.2.1   ECPM has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

   a)   Consistent with the quality policy;

   b)   Measurable;

   c)   Taken into account applicable requirements;

   d)   Relevant to conformity of products and services and to enhancement of customer satisfaction;

   e)   Monitored;

   f)   Communicated; and

   g)   Updated as appropriate.

ECPM maintains documented information on the quality objectives. (Dashboard)

6.2.2   When planning how to achieve its quality objectives, ECPM has determined:

   a)   What will be done;

   b)   What resources will be required;

   c)   Who will be responsible;

   d)   When it will be completed; and

   e)   How the results will be evaluated.

6.3   *Planning of Changes*

When ECPM determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

ECPM considers:

    a)   The purpose of the changes and their potential consequences;

    b)   The integrity of the quality management system;

    c)   The availability of resources; and

    d)   The allocation or reallocation of responsibilities and authorities.

7   Support

7.1   Resources

7.1.1   General

ECPM determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

ECPM considers:

    a)   The capabilities of, and constraints on, existing internal resources; and

    b)   What needs to be obtained from the external providers.

7.1.2   People

ECPM determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3   Infrastructure

ECPM determines, provides, and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

    a)   Buildings and associated utilities;

    b)   Equipment, including hardware and software;

    c)   Transportation resources; and

    d)   Information and communication technology.

7.1.4   Environment for the Operation of Processes

ECPM determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

    a)   Social (e.g. non-discriminatory, calm, non-confrontational);

    b)   Psychological (e.g. stress reducing, burnout prevention, emotionally protective);

    c)   Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5   Monitoring and Measuring Resources

7.1.5.1 General

ECPM determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

ECPM ensures that the resources provided:

   a)   Are suitable for the specific type of monitoring and measurement activities being undertaken; and

   b)   Are maintained to ensure their continuing fitness for their purpose.

ECPM retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by ECPM to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

   a)   Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standard exist, the basis used for calibration or verification is retained as documented information;

   b)   Identified in order to determine their status; and

   c)   Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

ECPM determines if the validity of previous measurement results has been adversely affected when measuring equipment is fount to be unfit for its intended purpose, and takes appropriate action as necessary.

7.1.6   Organizational Knowledge

ECPM determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, ECPM considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2   *Competence*

ECPM:

   a)   Determines the competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

   b)   Ensures that these persons are competent on the basis of appropriate education, training, or experience;

   c)   Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and

   d)   Retain appropriate documented information as evidence of competence *(See P-008)*.

7.3   *Awareness*

ECPM ensures that persons doing work under the ECPM's control are aware of:

a) The quality policy;

b) Relevant quality objectives;

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance; and

d) The implication of not conforming with the quality management system requirements.

7.4 Communication

ECPM determined the internal and external communications relevant to the quality management system, including:

a) On what it will communicate;

b) When to communicate;

c) With whom to communicate;

d) How to communicate; and

e) Who communicates.

7.5 Documented Information

7.5.1 General

ECPM's quality management system includes:

a) Documented information required by ISO 9001:2015; and

b) Documented information determined by ECPM as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating an updating documented information, ECPM ensures appropriate:

a) Identification and description (e.g. title, date, author, or reference number);

b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic); and

c) Review and approval for suitability and adequacy. *(See P-002)*

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015 are controlled to ensure:

a) Availability and suitable for use, where and when it is needed; and

b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, ECPM has addressed the following activities, as applicable.

a) Distribution, access, retrieval and use;

b) Storage and preservation, including preservation of legibility;

c) Control of changes (e.g. version control); and

d) Retention and disposition.

Documented information of external origin determined by ECPM to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

Documented information retained as evidence of conformity are protected from unintended alterations. Documented Information is controlled through procedure P-001.

8 Operation

8.1 Operational Planning and Control

ECPM planned, implemented and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and implemented the actions determined in Clause 6, by:

a) Determining the requirements for the products and services;

b) Establishing criteria for:

    1. The processes;

    2. The acceptance of products and services;

c) Determining the resources needed to achieve conformity to the product and service requirements;

d) Implementing control of the processes in accordance with the criteria; and

e) Determining and keeping documented information to the extent necessary:

    1. To have confidence that the processes have been carried out as planned;

    2. To demonstrate the conformity of products and services to their requirements.

The output of this planning is in a form suitable to ECPM's method of operations.

ECPM ensures that outsourced processes are controlled (See 8.4).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with Customers includes:

a) Providing information relating to products and services;

b) Handling inquiries, contracts or orders, including changes;

c) Obtaining customer feedback relating to products and services, including customer complaints;

d) Handling or controlling customer property; and

e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the product and services to be offered to customers, ECPM ensures that:

a) The requirements for the product and services are defined, including:

    a) Any applicable statutory and regulatory requirements;

    b) Those considered necessary by ECPM;

b) ECPM can meet the claims for the product and services it offers.

8.2.3   Review of Requirements Related to Products and Services

8.2.3.1   ECPM ensures that it has the ability to meet the requirements for products and services offered to customers. ECPM conducts a review before committing to supply products and services to a customer, to include:

  a)   Requirements specified by customer, including the requirements for delivery and post-delivery activities; (*Exclusion on post-delivery see P-006*)

  b)   Requirements not stated by the customer, but necessary for the specified intended use, when known;

  c)   Requirements specified by ECPM;

  d)   Statutory and regulatory requirements applicable to the products and services; and

  e)   Contract or order requirements differing from those previously expressed.

ECPM ensures that the contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by ECPM before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2   ECPM retains documented information, as applicable:

  a)   On the results of the review; and

  b)   On any new requirements for the products and services.

8.2.4   Changes to Requirements for Products and Services

ECPM ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3   Design and Development of Products and Services

ECPM does not design and develop products or services. *(See P-006)*.

8.4   Control of Externally Provided Processes, Products, and Services

8.4.1   General

ECPM ensures that externally provided processes, products, and services conform to requirements.

ECPM determines the control applied to externally provided processes, products, and services when:

  a)   Products and services from external providers are intended for incorporation into ECPM's own products and services;

  b)   Products and services are provided directly to the customer(s) by external providers on behalf of ECPM; and

  c)   A process, or part of a process, is provided by an external provider as a result of a decision by ECPM.

ECPM determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. ECPM retains documented information of these activities and any necessary actions arising from the evaluations *(See P-011)*.

8.4.2   Type of Extent Control

ECPM ensures that externally provided processes, products and services do not adversely affect ECPM's ability to consistently deliver conforming products and services to its customers.

ECPM:

    a)   Ensures that externally provided processes remain within the control of its quality management system;

    b)   Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

    c)   Takes into consideration:

        1.   The potential impact of the externally provided processes, products and services on ECPM's ability to consistently meet customer and applicable statutory and regulatory requirements;

        2.   The effectiveness of the controls applied by the external provider;

    d)   Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3   Information for External Providers

ECPM ensures the adequacy of requirements prior to their communication to the external provider.

ECPM communicates to external providers its requirements for:

    a)   The processes, products and services to be provided;

    b)   The approval of:

        1.   Products and services;

        2.   Methods, processes and equipment;

        3.   The release of products and services;

    c)   Competence, including any required qualification of persons;

    d)   The external providers' interactions with ECPM;

    e)   Control and monitoring of the external providers' performance to be applied by ECPM; and

    f)   Verification or validation activities that ECPM, or its customer, intends to perform at the external providers' premises.

8.5   Production and Service Provision

8.5.1   Control of Production and Service Provision

ECPM implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

    a)   The availability of documented information that defines:

        1.   The characteristics of the products to be produced, the services to be provided, or the activities to be performed;

        2.   The results to be achieved;

    b)   The availability and use of suitable monitoring and measuring resources;

    c)   The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;

    d)   The use of suitable infrastructure and environment for the operation of processes;

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Date printed 5/26/20 9:56 AM

M-001
Rev: B
Page: 17 of 22

e) The appointment of competent persons, including any required qualification;

f) The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) The implementation of actions to prevent human error; and

h) The implementation of release, delivery and post-delivery activities.

8.5.2   Identification and Traceability

ECPM uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

ECPM identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

ECPM controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

8.5.3   Property Belonging to Customers or External Providers

ECPM exercises care with property belonging to customer or external providers while it is under ECPM's control or being used by ECPM.

ECPM identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, ECPM reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4   Preservation

ECPM preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5   Post-delivery Activities

ECPM meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, ECPM considers:

a) Statutory and regulatory requirements;

b) The potential undesired consequences associated with its products and services;

c) The nature, use and intended lifetime of its products and services;

d) Customer requirements; and

e) Customer Feedback.

8.5.6   Control of Changes

ECPM reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

ECPM retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6   Release of Products and Service

ECPM has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer, do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer *(P-015)*.

ECPM retains documented information on the release of products and services. The documented information includes:

  a)   Evidence of conformity with the acceptance criteria;

  b)   Traceability to the person(s) authorizing the release.

8.7   Control of Nonconforming Outputs

8.7.1   ECPM ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

ECPM takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services *(See P-004)*.

ECPM deals with nonconforming outputs in one or more of the following ways:

  a)   Correction;

  b)   Segregation, containment, return or suspension of provision of products and services;

  c)   Informing the customer; and

  d)   Obtaining authorization for acceptance under concession.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2   ECPM retains documented information that:

  a)   Describes the nonconformity;

  b)   Describes the actions taken;

  c)   Describes any concessions obtained; and

  d)   Identifies the authority deciding the action in respect of the nonconformity.

9   Performance Evaluation

9.1   Monitoring, Measurement, Analysis and Evaluation

9.1.1   General

ECPM determines:

  a)   What needs to be monitored and measured;

  b)   The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

  c)   When the monitoring and measuring is performed;

  d)   When the results form monitoring and measurement are analyzed and evaluated.

ECPM evaluates the performance and the effectiveness of the quality management system.

ECPM retains appropriate documented information as evidence of the results.

9.1.2   Customer Satisfaction

ECPM monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. ECPM determines the methods for obtaining, monitoring and reviewing this information.

9.1.3   Analysis and Evaluation

ECPM analyzes and evaluates appropriate data and information arising form monitoring and measurement.

The results of analysis are used to evaluate:

    a)   Conformity of products and services;

    b)   The degree of customer satisfaction;

    c)   The performance and effectiveness of the quality management system;

    d)   If planning has been implemented effectively;

    e)   The effectiveness of actions taken to address risks and opportunities;

    f)   The performance of external providers; and

    g)   The need for improvements to the quality management system.

9.2   Internal Audit

9.2.1   ECPM conducts internal audits at planned intervals to provide information on whether the quality management system:

    a)   Conforms to:

        1.   ECPM's own requirements for its quality management system;

        2.   The requirements of ISO 9001:2015

    b)   Is effectively implemented and maintained. *(See P-003)*

9.2.2   ECPM has:

    a)   Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting ECPM, and the results of previous audits;

    b)   Defined the audit criteria and scope of each audit;

    c)   Selected auditors and conducts audits to ensure objectively and the impartiality of the audit process;

    d)   Ensured that the results of the audits are reported to relevant management;

    e)   Take appropriate correction and corrective actions without undue delay; and

    f)   Retain documented information as evidence of the implementation of the audit program and the audit results.

9.3   *Management Review*

9.3.1   General

Top management reviews ECPM's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of ECPM *(See P-007)*.

9.3.2   Management Review Inputs

Management review is planned and carried out taking into consideration:

    a) The status of actions from previous management reviews;

    b) Changes in external and internal issues that are relevant to the quality management system;

    c) Information on the performance and effectiveness of the quality management system, including trends in:

        1. Customer satisfaction and feedback from relevant interested parties;

        2. The extent to which quality objectives have been met;

        3. Process performance and conformity of products and services;

        4. Nonconformities and corrective actions;

        5. Monitoring and measurement results;

        6. Audit results;

        7. The performance of external providers;

    d) The adequacy of resources;

    e) The effectiveness of actions taken to address risks and opportunities (see 6.1); and

    f) Opportunities for improvement

9.3.3   Management Review Outputs

The outputs of the management review include decisions and actions related to:

    a) Opportunities for improvement;

    b) Any need for changes to the quality management system; and

    c) Resource needs.

ECPM retains documented information as evidence of the results of management reviews.

10   Improvement

10.1   General

ECPM determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

    a) Improving products and services to meet requirements as well as to address future needs and expectations;

    b) Correcting, preventing or reducing undesired effects; and

    c) Improving the performance and effectiveness of the quality management system.

10.2 *Nonconformity and Corrective Action*

10.2.1 When a nonconformity occurs, including any arising from complaints, ECPM:

    a) Reacts to the nonconformity and, as applicable:

        1. Takes action to control and correct it;

        2. Deals with the consequences;

    b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

        1. Reviewing and analyzing the nonconformity;

        2. Determining the causes of the nonconformity;

        3. Determining if similar nonconformities exist, or could potentially occur;

    c) Implements any action needed;

    d) Reviews the effectiveness of any corrective action taken;

    e) Updates risks and opportunities determined during planning, if necessary; and

    f) Makes changes to the quality management system, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered *(See P-005)*.

10.2.2 ECPM retains documented information as evidence of:

    a) The nature of the nonconformities and any subsequent actions taken; and

    b) The results of any corrective action.

10.3 *Continual Improvement*

ECPM continually improves the suitability, adequacy and effectiveness of the quality management system.

ECPM considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.