GPP QMS Manual

ISO 9001:2015E

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1.0 General

This manual provides an overview of the Greenfield Precision Plastics documented Quality Management System. Management is committed to the principles of Continuous Improvement and ISO9001:2015.

These principles enable Greenfield Precision Plastics to consistently provide products and services that meet customer, governmental, statutory, and regulatory requirements.

GPP management has played an active role in the development of the Quality Management System and support the policies as detailed in this manual.

Quality Management System documentation is maintained electronically, and printed copies of the Quality Manual, procedures, and work instructions are for reference only.

This manual is revised as necessary to reflect changes in quality system requirements.

2.0 Quality Management System References

International Standard ISO 9001:2015(E) “Quality Management Systems Requirements” was used as reference for the preparation of the Quality Management System, and of this document.

3.0 Quality Management System Definitions

This document utilizes the terms and definitions listed in ISO 9000:2015(E) “Quality Management Systems Fundamentals and Vocabulary”

4.0 Organization

4.1 Context of the Organization

Planning activities such as defining the needs and expectations of interested parties, scope of the QMS, the Quality Policy and determining internal and external issues affecting the organization's ability to achieve intended result(s) of the QMS, provide necessary input for defining the context of the organization.

The organization is committed to providing high quality products and services. The intended outcomes of the QMS are defined and documented in the Quality Policy, Quality Objectives and associated metrics provided in section nine of this document. External and internal issues identified as affecting the achievement of intended outcomes are documented in Appendix A of the QMS. Interested parties relevant to the organization are defined in section 4.2 of this document. The needs and expectations of these parties have been considered and are aligned with the Quality Policy, Quality Objectives and associated metrics.

The context of the organization is reviewed at least annually or when there is a significant change to operations or products

4.2 Relevant Interested Parties

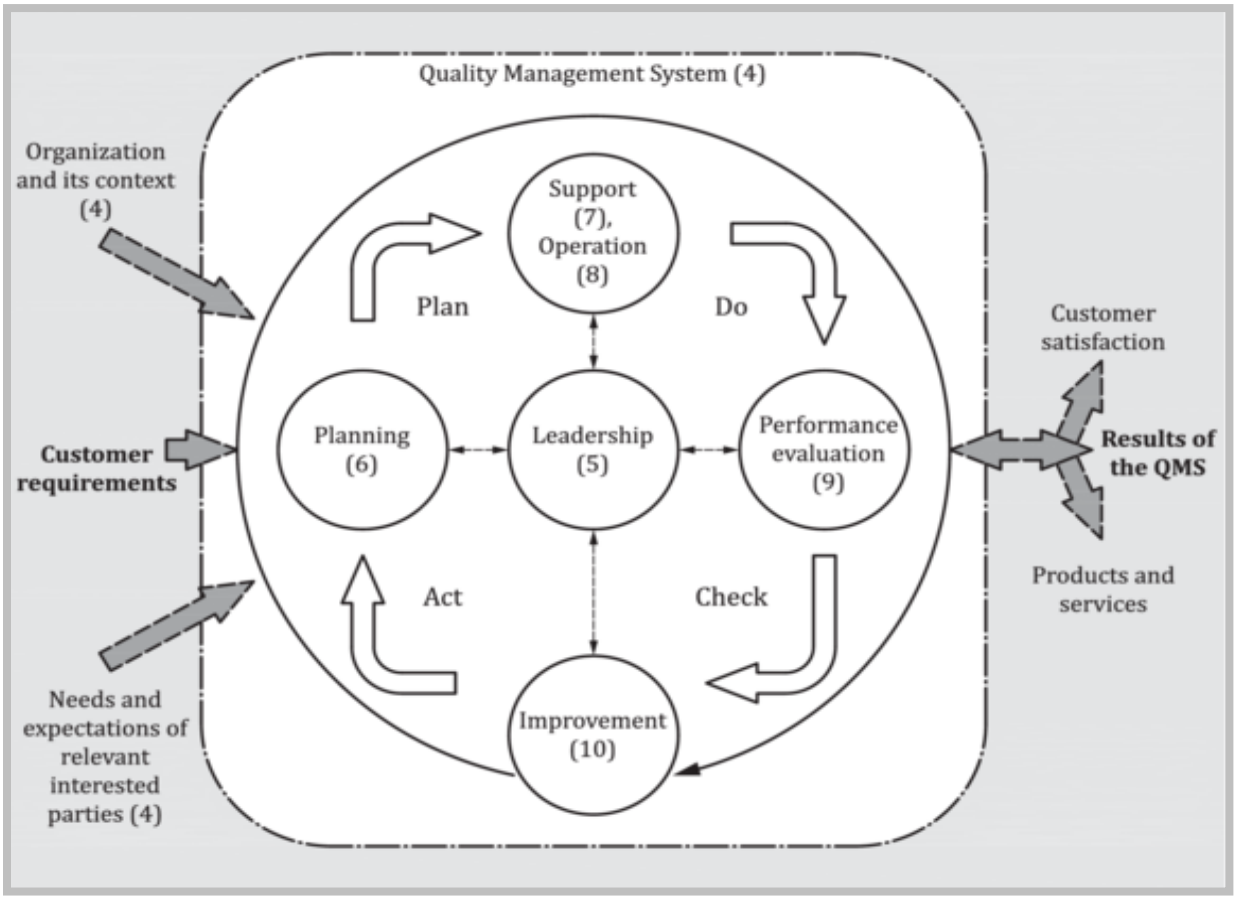
Relevant Interested parties are outlined and reviewed as part of our Context of the Organization Planning process. Requirements of interested parties are defined, monitored and updated as appropriate. Relevant Interested parties and their associated requirements are reviewed during Management Review meetings. Relevant Interested Parties and their requirements are identified below.

Owners	Return on Investment – Now and in the Future	Government Agencies	Compliance with Regulations, Tax Revenue
Management	Pay, Job Security, Good Work Environment	Local Community	Local Economic Benefit, Compliance, Tax Revenue
Employees	Pay, Job Security, Good Work Environment	Suppliers	On Time Payment, Strategic Partnership
Customers	Quality Products on Time Competitive & Low Risk	Customers / Customers	Quality Products on Time Competitive & Low Risk

4.3 Quality Management System

The Quality Management System utilizes a process approach, incorporating the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This approach enables the organization to plan processes and interactions. The PDCA cycle enables the organization to ensure processes are adequately resourced and managed, and opportunities for improvement are determined and addressed. Risk-based thinking enables the organization to determine the factors that could cause deviation from planned results, and to develop and implement preventive controls to minimize negative effects.

The Quality Management System is based on the requirements of ISO 9001:2015 and follows the Plan-Do-Check-Act improvement cycle



4.3.1 Scope

The QMS applies to all processes, activities and employees within Greenfield Precision Plastics; a custom plastic injection molding operation specializing in injection molding and auxiliary operations in accordance with OEM specifications and government regulations. Facilities within the Scope of the QMS includes the 40,000 SQ.FT. manufacturing operation located at 175 Industrial Park Drive, Greenfield, OH.

4.3.2 Management System Processes

Core and supporting processes are defined and the sequence and interaction of processes is provided in the IOP Diagram located in Appendix B of this document.

5.0 Leadership

5.1 Customer Focus

GPP management demonstrates leadership and commitment with respect to customer focus through ensuring that customer, statutory and regulatory requirements are defined, understood, and consistently met; risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; focus on enhancing customer satisfaction is maintained.

5.2 Quality Policy

Greenfield Precision Plastics is committed to achieving Customer Satisfaction by providing quality parts, on time, every time. We will accomplish this meeting all customer requirements and by continually improving our systems and quality performance.

In addition, GPP will meet all applicable ISO 9001 and regulatory requirements, and will ensure this policy is implemented, communicated, and is understood throughout the organization.

5.3 Organizational Roles, Responsibilities and Authorities

Top Management is responsible for endorsing the Quality policy, ensuring appropriate resource allocation to enable the effective operation and continual improvement of the QMS.

In addition, the company's management is responsible for:

a) Establishing and communicating the Quality Policy throughout the organization.
b) Defining and communicating responsibilities relating to the Quality Management System.
c) Conducting formal reviews of the QMS, sharing internal audit results and ensuring continued conformance and effectiveness of the QMS.
d) Continuing to make improvements with respect to the Quality Management System.
e) Ensuring that appropriate resources are available, and employees qualified to perform activities. in accordance with the Quality Management System.
f) Ensuring that Quality objectives are established and monitored for achievement.

5.3.1 Delegation of Responsibility

An organizational chart Appendix C has been established to show the interrelations of personnel within the organization. Top Management may delegate specific responsibility and authority as necessary. Top management assigns the roles, responsibilities and authorities for reporting on the performance of the QMS and its processes. Detailed descriptions of the responsibilities, authority and interrelation of different areas are described in the relevant procedures.

5.4 Communication

GPP Management determines the internal and external communications relevant to the quality management system, including; what to communicate; when to communicate; with whom to communicate; how to communicate; and who provides the communication.

5.4.1 Internal Communication

Internal Communication includes the Quality Policy, Quality Objectives, safety systems / requirements, and applicable authorities and responsibilities. Additional internal communications are defined in this and other QMS documentation.

5.4.2 External Communication

Company management is responsible for determining external communications relevant to the QMS, product specific documentation and shareholder information.

6.0 Management System Planning

GPP management evaluates internal and external issues to identify strengths, weaknesses, opportunities, and threats as inputs for developing strategic goals. The outcome of this activity is to develop a Quality Management System, with measurable objectives, and plans to achieve the objectives.

Planning activities for the Quality Management System focuses on effectively meeting customer requirements, quality objectives, and legal requirements. In addition, planning activities identify risks and opportunities in ensure:

a) Actions are integrated and implemented into processes
b) The Quality Management System can achieve its intended results
c) Desirable effects will be enhanced
d) Undesired effects will be reduced or prevented
e) Improvement is fostered
f) Effectiveness of actions are evaluated

6.1 Risks and Opportunities

GPP management has considered risks and opportunities as they relate to the context of the organization and interested-party expectations. Actions are taken to address risks and opportunities in relation to achieving intended results and planned objectives. Actions taken to address risks and opportunities are proportionate to the potential impact on the QMS.

6.2 Quality Objectives

GPP Management defines measurable and time-based quality objectives for relevant functions and levels within the organization. The objectives are monitored by the management team and are formally reviewed and updated during the management review meeting. Quality objectives are consistent with the Quality Policy, prescribed to all levels and functions within the organization, and include consideration of applicable requirements, relevance to conformity of products and services, and enhancement of customer satisfaction.

Plans to achieve quality objectives, including responsibilities, timing, and resources for the realization of the objectives are defined and documented.

6.3 Planning Changes

Potential changes to the QMS are evaluated by the management team. Several tools are used to assist in the evaluation of the change, such as Management Review, Corrective Action review, QMS manual review, and review of results. The evaluation process includes review of the purpose for the change, potential consequences, impact on the QMS, availability of resources, and the assignment/reassignment of responsibilities and authority as defined in SOP-ADM-004

7.0 Resources

7.1. Resources

GPP determines and provides resources needed for establishment, implementation, maintenance, and continual improvement of the Quality Management System. These resources include the necessary:

a) People
b) Infrastructure
c) Environment for the Operation of Processes
d) Monitoring and Measurement Resources
e) Measurement Traceability
f) Organizational Knowledge

7.1.1 People

The Management Team will determine and provide personnel necessary for the effective implementation and operation of Quality Management System processes to achieve objectives, and operation and control of processes.

7.1.2 Infrastructure

The management team determines, provides and maintains the infrastructure necessary for the operation of processes and to achieve conformity of products and services.

Infrastructure includes:

a) buildings and associated utilities
b) equipment, including hardware and software
c) transportation resources
d) information and communication technology

Environment for the Operation of Processes

The management team determines, provides and maintains an environment necessary for the operation of processes and to achieve conformity of products and services. This environment includes, but is not limited to safety, regulatory and statutory regulations.

7.1.4 Monitoring and Measurement Resources

GPP 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.

GPP manages the measuring and test device equipment calibration program to ensure that monitoring and measurement activities are conducted according to defined procedures (SOP-QA-002). Documented information is retained as evidence of fitness for purpose of the monitoring and measurement resources.

Measuring equipment is:

a) calibrated or verified, or both, at specified intervals, or prior to use, using measurement standards traceable to international or national measurement standards; when standards do not exist, records for the basis used for calibration are retained**.**
b) identified in order to determine status.
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

7.1.5 Organizational Knowledge

The management team determines the knowledge necessary for the operation of processes and to achieve conformity of products and services. This knowledge is maintained, made available to the extent necessary, and is defined further in section 7.2 of this document.

7.2. Competence

GPP provides the necessary staff with the needed knowledge and skills, organizational infrastructure, and financial resources for establishing, implementation, maintenance, and improvement of the QMS. In cases where it is deemed necessary, GPP will hire competent external personnel and organizations from relevant fields for realization of activities for which the organization does not have adequate resources.

Management is responsible for identifying the needs and conducting training of employees who carry out activities that may have a significant impact on the quality of product, service and customer satisfaction.

Each department manager/process owner is responsible for ensuring the competency of employees on the basis of education, training, and/or work experience—in accordance with the requirements of the work being performed. Defined in SOP-HR-001

The method of ensuring the necessary competencies for roles, responsibilities, and authorities for implementation and control activities within the QMS are established.

7.3. Awareness

GPP management ensures that *people doing work under its control* are aware of the Quality Policy, relevant quality objectives, their contribution to the effectiveness of the QMS, and implications of nonconformance with the QMS requirements.

8.0 Operation

8.1 Operational Planning

Greenfield Precision Plastics plans, implements and controls processes as required for the provision of products and services, and to implement the actions determined in planning activities. To achieve this, GPP determines the requirements for the products and services to be provided and establishes acceptance criteria for both the processes and the acceptance of products and services.

In addition, Greenfield Precision Plastics:

a) Establishes the resources required to achieve conformity to the product and service requirements.
b) Controls the processes in accordance with the established criteria.
c) Determines, maintains and retains documented information appropriately, in order to have confidence that the processes have been executed as planned and to demonstrate the conformity of products and services to identified requirements.

The output of this planning is appropriate to GPP operations and any changes are planned and controlled. In addition, reviews are conducted into the consequences of unintended changes, including the taking of any necessary action to mitigate any adverse consequences.

8.2 Requirements for Product & Service

8.2.1 Customer communication

Communication with customers includes:

a) providing information relating to products and services.
b) handling enquiries, contracts or orders, including changes.
c) obtaining customer feedback relating to products and services, including complaints.
d) handling or controlling customer property.
e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements related to products and services

GPP ensures requirements for the products and services to be offered to customers are defined by conducting a review of the requirements before committing to supply the products or services.

This activity includes a review of:

a) requirements specified by the customer, including those for delivery and post-delivery activities.
b) requirements not stated by the customer but known by GPP and necessary for the ended use.
c) statutory and regulatory requirements applicable to the products and services.
d) contract or order requirements differing from those previously expressed.

GPP ensures that contract or order requirements differing from those previously defined are resolved, and retains documented information, as applicable, on results of the review and on any new requirements for products and services. The process is defined in SOP-SLS-001

8.2.3 Changes to requirements for products and services

When requirements for products and services are changed, relevant documented information is amended, and relevant persons are made aware of the changed requirements.

8.3 Design and Development

All product design and development activities are defined and documented in Procedure (SOP-ENG-001).

Design and Development activities include:

8.3.1 Design and Development Planning

Plans are prepared for each design and development activity, which describe the activity, and define the responsibility for implementation. These activities are assigned to qualified personnel equipped with adequate resources. The plans are updated as necessary, as the design evolves.

The organizational and technical interfaces between different groups, which provide input into the design process, are defined and the necessary information documented, communicated, and regularly reviewed.

8.3.2 Design and Development Inputs

Design input requirements, including applicable statutory and regulatory requirements, are identified, documented, and reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved. The results of proposal, tender and contract review activities are taken into consideration.

8.3.3 Design and Development Controls

Formal reviews of the design are planned and conducted at appropriate stages of the design. Participants include representatives of all functions concerned with the design stage being reviewed, as well as other specialists as required. Documented information of the reviews is maintained.

GPP controls the design and development process to ensure that:

a) the results to be achieved are defined.
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements.
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements.
d) validation activities are conducted to ensure that the resulting products and services meet the
e) requirements for the specified application or intended use.
f) any necessary actions are taken on problems determined during the reviews, or verification and validation activities.

8.3.4 Design and development outputs

GPP ensures design and development outputs:

a) meet the input requirements
b) are adequate for the subsequent processes for the provision of products and services
c) include or reference monitoring and measuring requirements and acceptance criteria
d) specify the characteristics of products and services that are essential for their intended purpose
e) and their safe and proper provision.

Documented information relating to design and development outputs is retained

8.3.5 Design and development changes

GPP identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to ensure that there is no adverse impact on conformity to requirements.

Retained documented information includes:

a) design and development changes
b) the results of reviews
c) the authorization of the changes
d) the actions taken to prevent adverse impacts

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

GPP evaluates subcontractors / suppliers and purchases only from those that can satisfy quality requirements. GPP has established and implemented a process for the evaluation of subcontractors / suppliers based on defined criteria. The process is defined in SOP-MTLS-001

Criteria includes:

a) Ability to understand product requirements
b) Capability to meet specifications
c) Logistical capacity
d) Adequate Quality Management System
e) Sound financial position
f) Has achieved ISO 9001 certification or passed a second party audit.

An approved supplier list is maintained. Orders may only be placed with suppliers on the list.

8.4.2 Type and extent of control

The type and extent of control exercised over subcontractors is dependent on the impact of the subcontracted product on the quality of the final product, and the subcontractors' prior quality performance.

Purchased products may be subjected to receiving inspection. Performance of receiving inspection and the quantity / sample size inspected is dependent on the suppliers' prior quality performance, and the ability to perform an adequate receiving inspection. Where incoming inspection is not feasible or desirable, supplier certifications may be utilized.

Nonconforming products are segregated and are prevented from use in production.

Supplier performance is monitored. Suppliers with unacceptable performance are required to implement corrective action and are discontinued if there is no improvement.

8.4.3 Information for external providers

Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release.

8.5 Product & Service Provision

The availability of specifications that define the characteristics of the product are defined as part of the order acceptance process. The availability of clearly understandable process related information / documentation for subsequent activities necessary for achieving product conformity is provided.

The following items are implemented to maintain control of production processes:

a) The availability of information describing product characteristics
b) The availability of procedures / work instructions
c) The use of suitable and capable equipment
d) The availability of monitoring and measuring devices
e) The implementation of monitoring and measurement processes
f) The implementation of defined release, delivery and post-delivery activities

8.5.1 Control of Production

GPP operates under controlled conditions.

Controlled conditions include:

a) The availability of documented information that defines the characteristics of the products to be produced, the services to be provided, the activities to be performed, and the results to be achieved
b) Criteria for workmanship and competence, effectively trained personnel and adequate equipment
c) The availability and use of suitable monitoring and measuring resources; 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

Note: No special processes have been identified within the organization

8.5.2 Identification and traceability

GPP identifies outputs to ensure the conformity and status of products and services with respect to monitoring and measurement requirements throughout production process.

GPP 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

GPP exercises care with property belonging to customers or external providers while under its control. This activity includes the identification, verification, and protection of the property.

8.6 Product Release

Processes have been implemented to ensure requirements have been satisfactorily completed prior to releasing product to the customer.

Documented information is retained to evidence this activity. The documented information includes evidence of conformity with the acceptance criteria and the release authority.

8.7 Non-Conforming Outputs

8.7.1 General

GPP ensures that outputs that do not conform to defined requirements are identified and controlled to prevent unintended use or delivery.

GPP takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This action also applies to nonconforming products and services detected during or after the delivery / provision of products or services. The process is defined in SOP-QA-005

GPP handles 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;
d) obtaining authorization for acceptance under concession

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

8.7.2 GPP retains documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity

Tags, labels and quarantine is used to identify and segregate nonconforming / suspect product.

8.8 Emergency Preparedness / Response

Emergency preparedness and response plans have been developed to identify potential accidents and emergencies, and to deal with unexpected incidents.

Responsibilities and information sources are clearly defined, as well as the actions to be followed in the event of an emergency.

Testing of the effectiveness of the plans is undertaken on a periodic basis. Records are maintained to demonstrate the test methods, results and any corrective actions taken to improve the plans.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

GPP Management determines:

a) what needs to be monitored and measured;
b) methods for monitoring, measurement, analysis / evaluation needed to ensure valid results;
c) when the monitoring and measuring is performed;
d) when the results from monitoring and measurement are analyzed and evaluated.

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

GPP retains appropriate documented information as evidence of the results.

9.1.2 Quality Performance Indices

GPP collects and analyses appropriate data to demonstrate the suitability and effectiveness of the QMS and to and to identify opportunities for improvement. Data is presented during management review. Data includes results from monitoring and measuring product conformity, customer satisfaction, planning effectiveness, risk assessment, and vendor performance.

9.1.3 Customer Satisfaction

GPP monitors information relating to customer perception of …requirements. …Collecting and analyzing reviewing customer feedback, complaints, and customer satisfaction is conducted during management review. Customer satisfaction data is used by management to identify opportunities for improvement

9.2 Internal Audit

Internal audits are conducted at planned intervals to evaluate the effectiveness of the QMS, and to verify the QMS conforms to the requirements of ISO 9001:2015. The process is defined in SOP-QA-003

The audit team consists of trained auditors, who are impartial to the process and have the necessary competence to identify non-conformances and opportunities for improvement within the QMS.

Audit reports and recommendations for corrective action are provided to GPP management. Corrective actions are implemented and verified. Audit findings and associated corrective actions are reviewed during Management Review meetings.

Internal Audit findings and corrective action information is retained.

9.3 Management Review

9.3.1 General

The Management Team meets twice per year to review the status of the QMS. The quality policy and manual are reviewed for suitability and effectiveness annually based on Key Process Indicators and internal audit findings. The process is defined in SOP-ADM-002

9.3.2 Management Review Inputs:

a) The status of actions from previous management reviews;

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

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

- Customer satisfaction and feedback from relevant interested parties;
- The extent to which quality objectives have been met;
- Process performance and conformity of products and services;
- Nonconformities and corrective actions;
- Monitoring and measurement results;
- Audit results;
- The performance of external providers,
- The adequacy of resources;
- Effectiveness of actions taken to address risks and opportunities;
- 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
c) Resource needs.

GPP retains documented information as evidence of the results of management reviews. Decisions and required actions are documented in management review meeting notes as management review action items.

10.0 Improvement

10.1 General

GPP determines and selects opportunities for improvement and implements actions to meet customer requirements and enhance customer satisfaction.

This activity includes improving products and services to meet requirements as well as to address future needs and expectations; correcting, preventing or reducing undesired effects; improving the performance and effectiveness of the quality management system

10.2 Non-Conformity and Corrective Action

When a nonconformity occurs, including any arising from complaints, GPP takes action to eliminate the cause of nonconformity and prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities.

Examples of actions taken include:

- taking action to control and correct the non-conformity;
- reviewing and analyzing the nonconformity;
- determining the causes of the nonconformity;
- determining if similar nonconformities exist, or could potentially occur;
- implementation of any action needed;
- review of the effectiveness of any corrective action taken;
- updating risks and opportunities;
- If necessary, making changes to the QMS.

Documented information is retained as evidence of the nature of the nonconformities, corrective actions taken, and the results of corrective actions. As defined in SOP-QA-004

10.3 Continual improvement

GPP continually improves the suitability, adequacy and effectiveness of the Quality Management System by considering the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities for continual improvement.