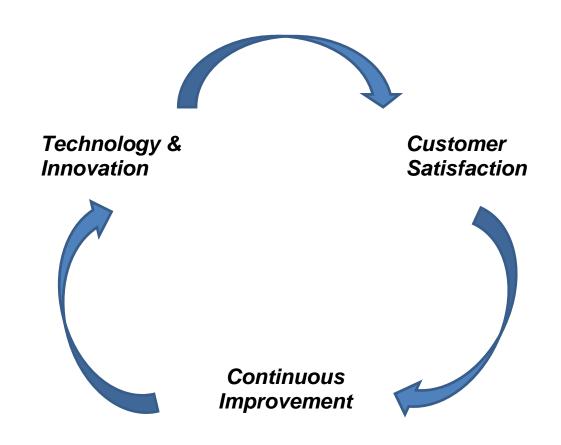
GTG Inc.

ISO 9001:2008 QMS Manual



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- 7.0 Product Realization
- 8.0 Measurement, Analysis & Improvement

Our Quality Systems Manual is designed to support our Quality Management System and the ISO 9001:2008 standard.

	Revision Log						
Date	Revision	Issue	Approved				
12/14/2011	0	Unreleased Draft	G.K. / D.P.				
8/28/2012	1	Released Draft	G.K. / D.P.				
5/21/2013	Α	Released	G.K. / D.P.				

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Introduction

This manual describes the quality management policies and references the procedures established and implemented at GTG.



Company Background

Established in 1978, GTG Inc. is a full service precision machining facility. We offer contract machining, assembly and various engineering services and support customers from many diverse industries including Analytical Instrumentation, Biopharmaceutical, Medical, Semi-Conductor, Defense and Telecommunications. We are capable of providing a wide range of services in our well-equipped 20,000 square foot facility.

A family-owned business, GTG Inc. will strive to meet your manufacturing needs and exceed your expectations, understanding that your processes depend on quality, on-time delivery, accurate pricing and flexibility. Please don't hesitate to call with any project large or small, simple or complex.

We work with a wide variety of metals and plastics; including but not limited to: Aluminum, Stainless Steel, Tungsten, Teflon, Nylon, Vespel, Peek, Delrin, 17-4 PH, MIC-6 Cast Plate, etc.

GTG Inc. employs dedicated people in our operations, all with a deep sense of pride in their craftsmanship with a common goal to achieve customer satisfaction by providing quality workmanship and on time delivery.

All customers, whatever the size of the order, are served with the philosophy that their satisfaction means our continued success.

The GTG Inc. Quality System complies with the requirements of ISO 9001:2008 and effectively describes the controls used to assure customer Contract and /or purchase order compliance in all aspects of Purchasing, Manufacturing, Engineering, and Quality Control operations to provide a quality product at a reasonable price.

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Core Products & Business Processes





TURNING

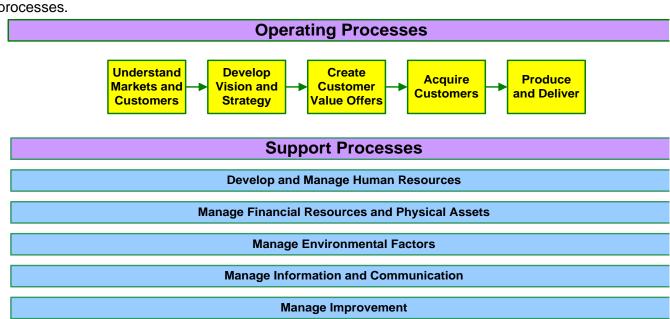
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ASSEMBLIES

Business Processes Framework

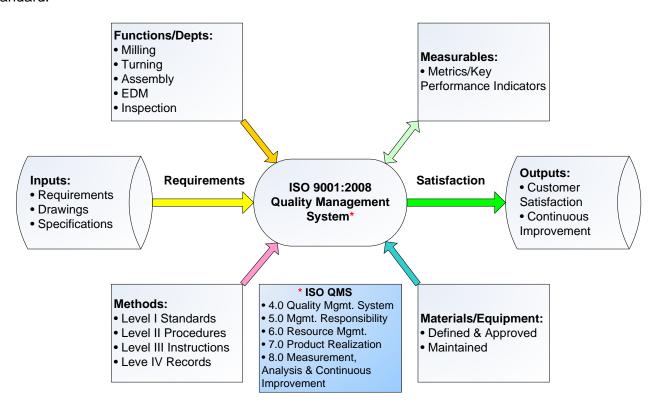
GTG business processes are grouped into five (5) primary operating processes and five (5) support processes.



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Description of Quality System

The GTG quality system is designed to ensure that core business processes are adequately integrated with other pertinent processes and sub-processes, so that together that they meet the requirements described in the ISO 9001:2008 standard for quality systems. The basis for integrating pertinent processes is best understood by referring to the model below, which is adapted from the ISO 9001:2008 standard.



1.0 QMS System

The GTG QMS Manual and all associated procedures define our "Quality Management System" for compliance to ISO 9001:2008. Our QMS Manual promotes the adoption of a process approach when developing, implementing and continuously improving the effectiveness of our quality management system, while enhancing our customer satisfaction and meeting our customer requirements.

2.0 SCOPE

GTG Inc. offers precision-machined 5 axis components, mechanical assemblies, and engineering services to customer purchase orders and specifications.

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2.1 Exclusions:

GTG Inc. is a contract manufacturing company who only supplies products manufactured to customer supplied specifications and takes exceptions to the following clauses:

- a) Design & Development Clause 7.3
- b) Post Delivery Service Clause 7.5.1.4 except B

2.2 Locations

GTG operates a single location at 3 Birch Road, Middleton, MA 01949.

2.3 GTG Mission Statement

Our Mission is to create a partnership with our customers to provide them with the quality, pricing and delivery requirements we both need to succeed now, and in the future.

We are committed to providing a safe and secure workplace and maintaining a fair and honest relationship with our employees, customers and suppliers in order to attain this goal.

2.4 GTG Quality Policy

GTG is committed to customer satisfaction by consistently providing products that meet or exceed the requirements and expectations of our customers.

The Management of GTG Inc. and its employees are committed to complying with the requirements of our ISO 9001:2008 Quality Management Systems and will achieve continual improvement through our internal quality auditing and management review system.

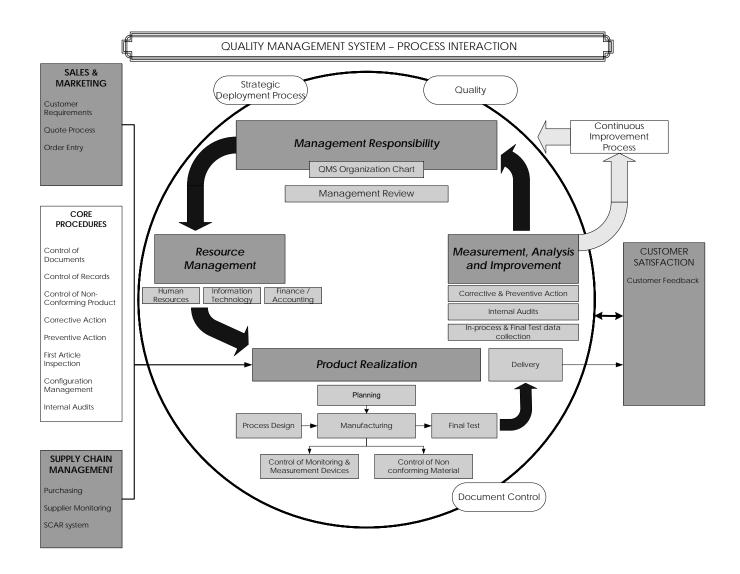
This Quality Policy is communicated to our employees and is reviewed for continuing suitability.

2.5 GTG Quality Objectives

Are established annually and are reviewed monthly

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3.0 Process Based Quality Management System – Core Process



Note: In addition, the continuous improvement methodology known as Plan-Do-Check-Act (PCDA) can be applied to all processes. PCDA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and GTG's policies.

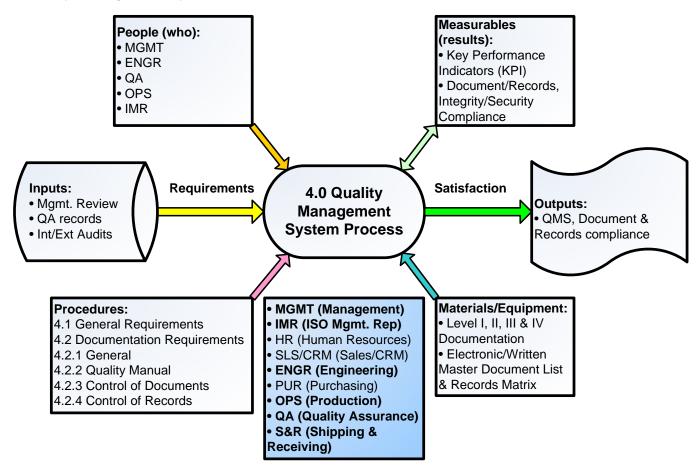
Do: implement the processes

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

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4 Quality management system



4.1 General requirements

GTG shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

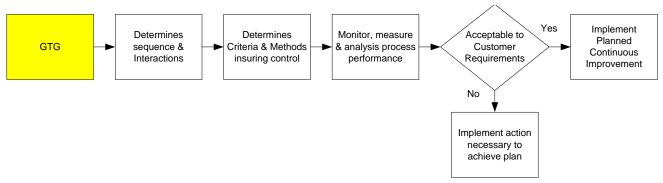
GTG shall

- a) Determine the processes needed for the quality management system and their application throughout GTG (see 1.2),
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitor, measure where applicable, and analyze these processes, and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by GTG in accordance with the requirements of this International Standard.

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Where an organization chooses to outsource any process that affects product conformity to requirements, GTG shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

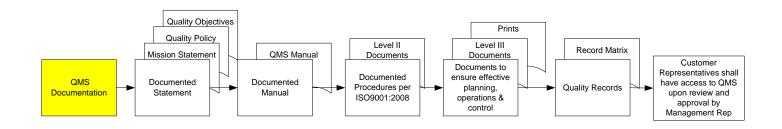


4.2 Documentation requirements

4.2.1 General

The GTG quality management system documentation shall include

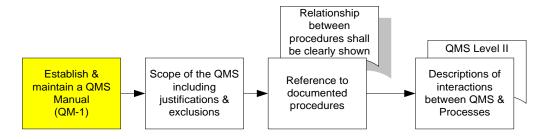
- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual,
- c) Documented procedures and records required by this International Standard, and
- d) Documents, including records, determined by GTG to be necessary to ensure the effective planning, operation and control of its processes.



4.2.2 Quality manual

GTG shall establish and maintain a quality manual that includes:

- a) The scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) The documented procedures established for the quality management system, or reference to them.
- c) A description of the interaction between the processes of the quality management system.



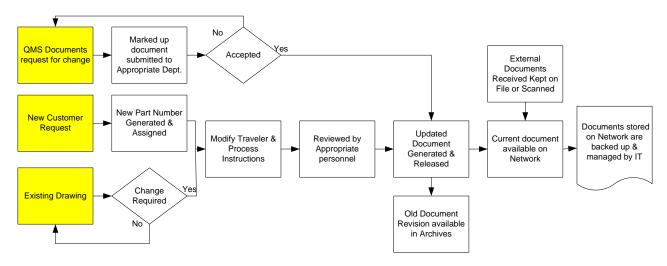
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4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by GTG to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

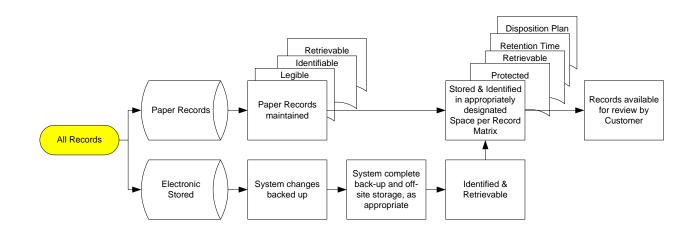


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4.2.4 Control of records

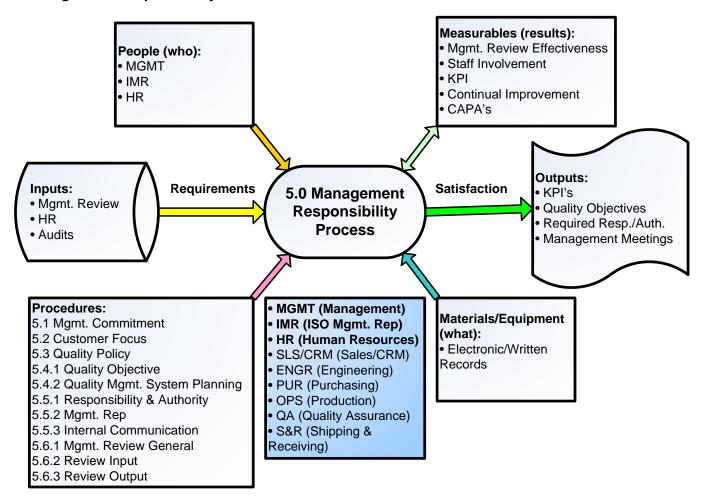
Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

GTG shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.



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5 Management Responsibility

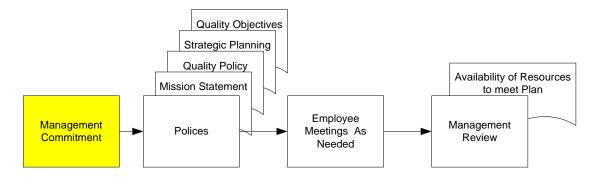


5.1 Management commitment

GTG top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

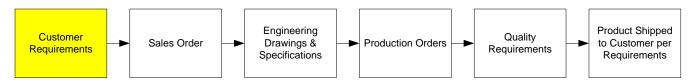
- a) Communicating to GTG the importance of meeting customer as well as statutory and regulatory requirements,
- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

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5.2 Customer focus

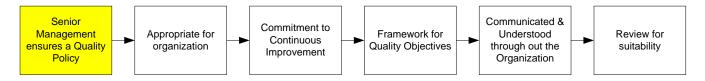
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).



5.3 Quality policy

GTG top management shall ensure that the quality policy

- a) Is appropriate to the purpose of GTG,
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within GTG, and
- e) Is reviewed for continuing suitability.

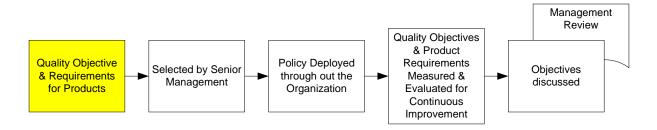


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5.4 Planning

5.4.1 Quality objectives

GTG top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within GTG. The quality objectives shall be measurable and consistent with the quality policy.



5.4.2 Quality Management System Planning

GTG top management shall ensure that

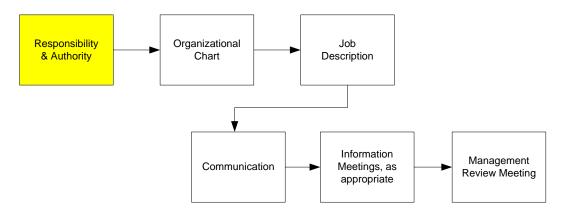
- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1 as well as the quality objectives and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.



5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

GTG top management shall ensure that responsibilities and authorities are defined and communicated within GTG.



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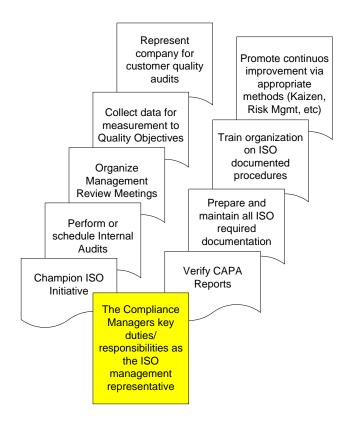
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5.5.2 Management Representative

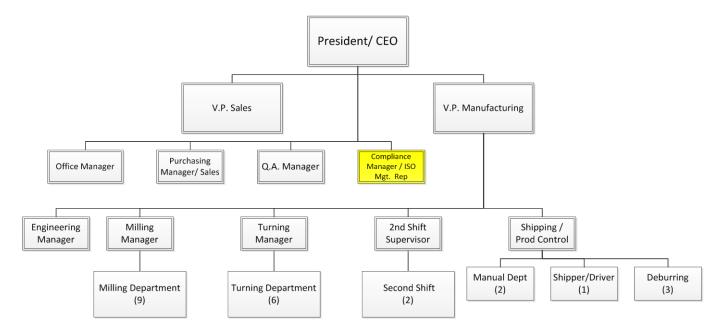
GTG top management shall appoint a member of GTG's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of awareness of customer requirements throughout GTG.

At GTG, this person is the Compliance Manager.

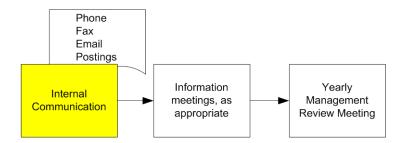


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5.5.3 Internal communication

GTG top management shall ensure that appropriate communication processes are established within GTG and that communication takes place regarding the effectiveness of the quality management system.



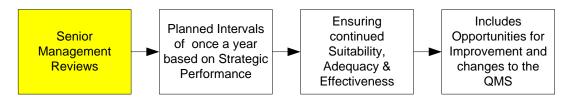
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5.6 Management review

5.6.1 General

GTG top management shall review GTG's quality management system, at planned intervals - annually, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

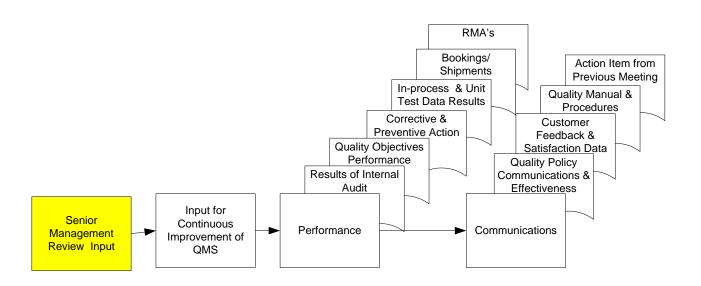
Records from management reviews shall be maintained (see 4.2.4).



5.6.2 Review input

The input to management review shall include information on

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement.

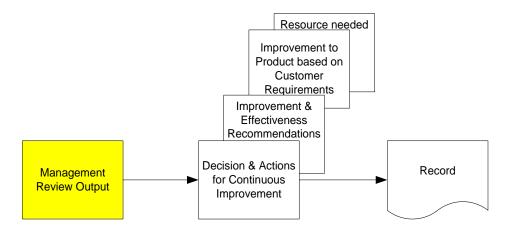


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5.6.3 Review output

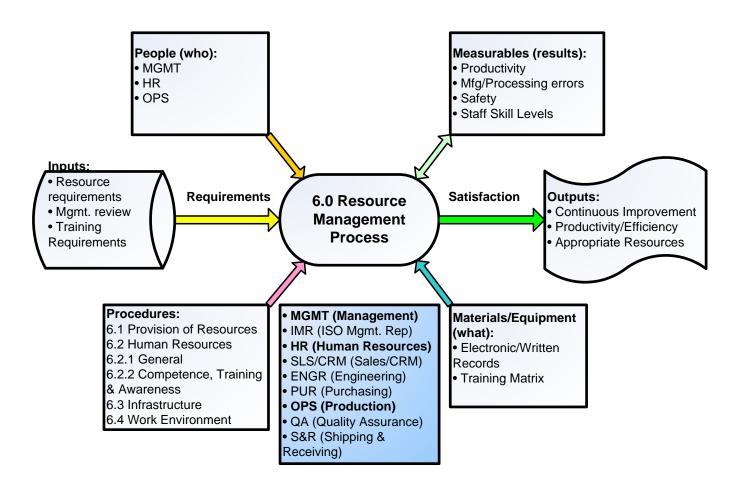
The output from the GTG management review shall include any decisions and actions related to

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.



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6.0 Resource Management

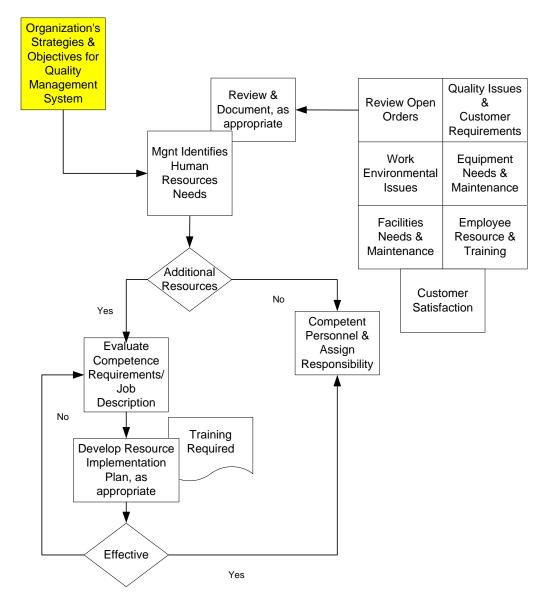


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6.1 Provision of resources

GTG shall determine and provide the resources needed to

- a) Implement and maintain the quality management system and continually improve its effectiveness and
- b) Enhance customer satisfaction by meeting customer requirements.

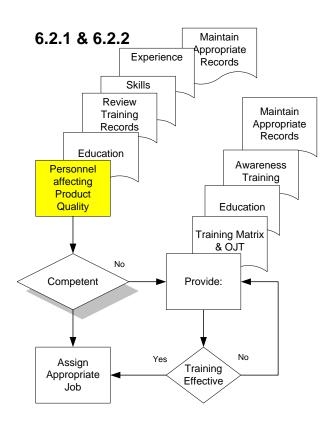


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6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.



6.2.2 Competence, training and awareness

GTG shall

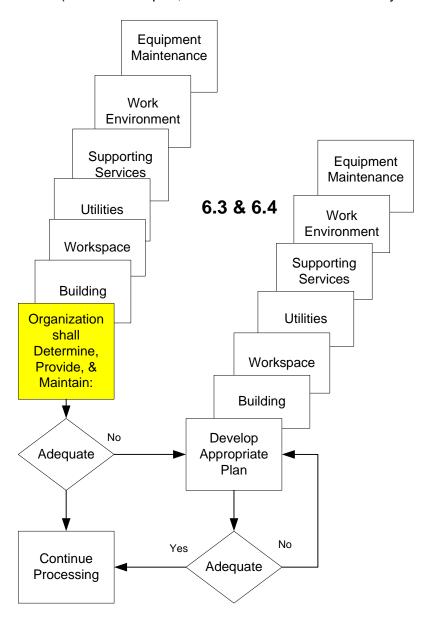
- a) Determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) Where applicable, provide training or take other actions to achieve the necessary competence,
- c) Evaluate the effectiveness of the actions taken,
- d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) Maintain appropriate records of education, training, skills and experience (see 4.2.4).

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6.3 Infrastructure

GTG shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

- a) Buildings, workspace and associated utilities,
- b) Process equipment (both hardware and software), and
- c) Supporting services (such as transport, communication or information systems).

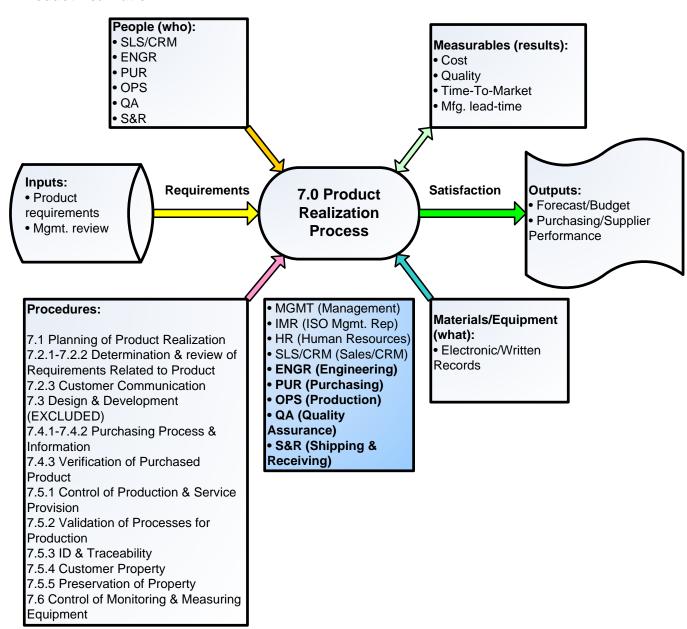


6.4 Work environment

GTG shall determine and manage the work environment needed to achieve conformity to product requirements.

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7 Product Realization



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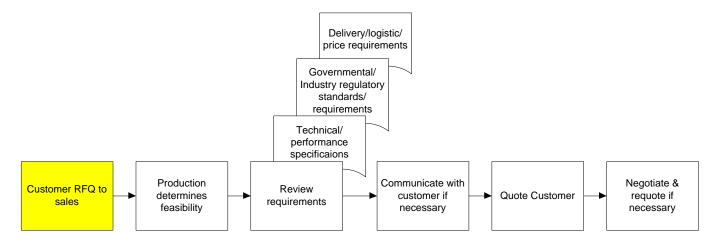
7.1 Planning of product realization

GTG shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, GTG shall determine the following, as appropriate:

- a) Quality objectives and requirements for the product;
- b) The need to establish processes and documents and to provide resources specific to the product,
- c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for GTG's method of operations.



7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

GTG shall determine

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities.
- b) Requirements not stated by the customer but necessary for specified or intended use, where known.
- c) Statutory and regulatory requirements applicable to the product, and
- d) Any additional requirements considered necessary by GTG.

7.2.2 Review of requirements related to the product

GTG shall review the requirements related to the product. This review shall be conducted prior to GTG's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved, and

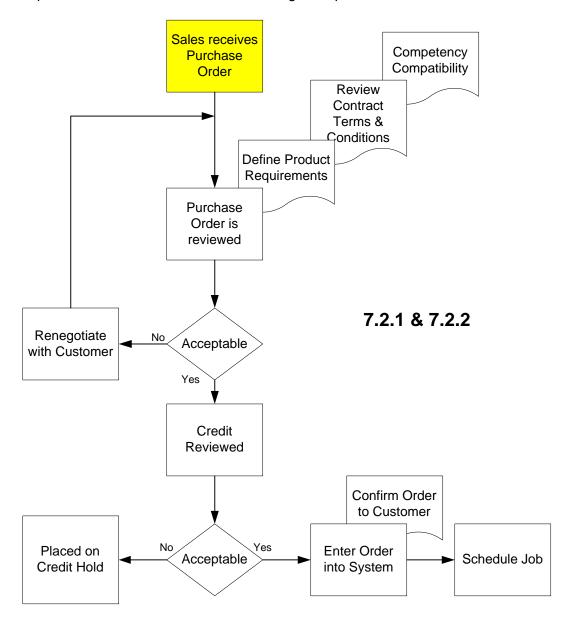
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c) GTG has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by GTG before acceptance.

Where product requirements are changed, GTG shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

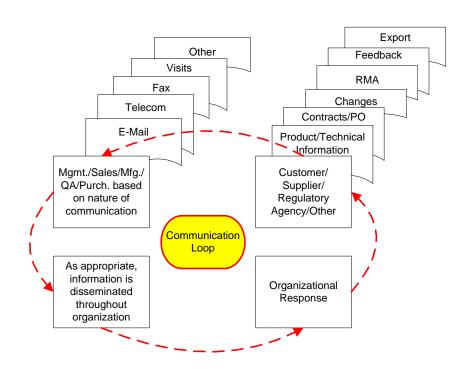


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7.2.3 Customer communication

GTG shall determine and implement effective arrangements for communicating with customers in Relation to

- a) Product information,
- b) Inquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.



7.3 Design and development

GTG does not perform product design and development. Therefore section 7.3 is excluded in its entirety.

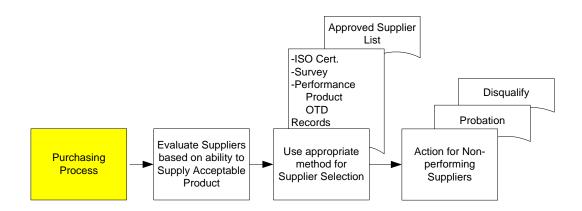
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7.4 Purchasing

7.4.1 Purchasing process

GTG shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

GTG shall evaluate and select suppliers based on their ability to supply product in accordance with GTG's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4). GTG Shall develop and annually review the performance placed onto the Approved Supplier List.



7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel, and
- Quality management system requirements.

GTG shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

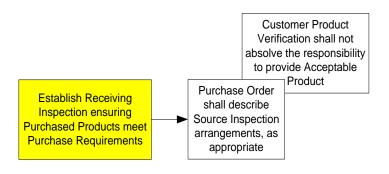


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7.4.3 Verification of purchased product

GTG shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where GTG or its customer intends to perform verification at the supplier's premises, GTG shall state the intended verification arrangements and method of product release in the purchasing information.

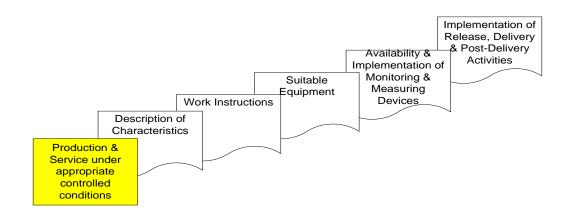


7.5 Production and service provision

7.5.1 Control of production and service provision

GTG shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions, as necessary,
- c) The use of suitable equipment.
- d) The availability and use of monitoring and measuring equipment,
- e) The implementation of monitoring and measurement, and
- f) The implementation of product release, delivery and post-delivery activities.
- g) Per contractual requirements dimension shall be recorded.



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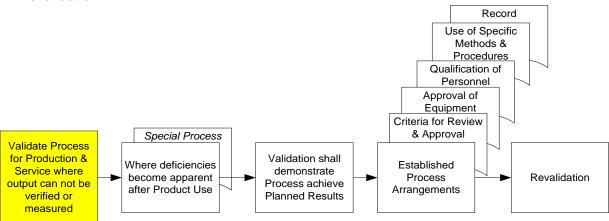
7.5.2 Validation of processes for production and service provision

GTG shall validate any processes for production provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

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

GTG shall establish arrangements for these processes including, as applicable,

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records (see 4.2.4), and
- e) Revalidation.

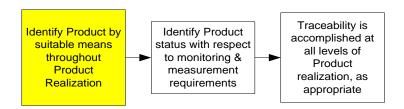


7.5.3 Identification and traceability

Where appropriate, GTG shall identify the product by suitable means throughout product realization.

GTG shall identify the product status with respect to monitoring and measurement requirements throughout product realization, as customer contractually specified. Product status is verified via the Job Boss Traveler.

Where traceability is a requirement, GTG shall control the unique identification of the product and maintain records (see 4.2.4).



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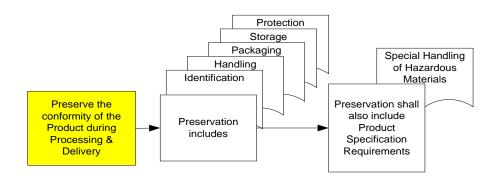
7.5.4 Customer property

GTG shall exercise care with customer property while it is under GTG's control or being used by GTG. GTG shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, GTG shall report this to the customer and maintain records (see 4.2.4). GTG accomplishes identification via Job Boss software.



7.5.5 Preservation of product

GTG shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.



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7.6 Control of monitoring and measuring equipment

GTG shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

GTG shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

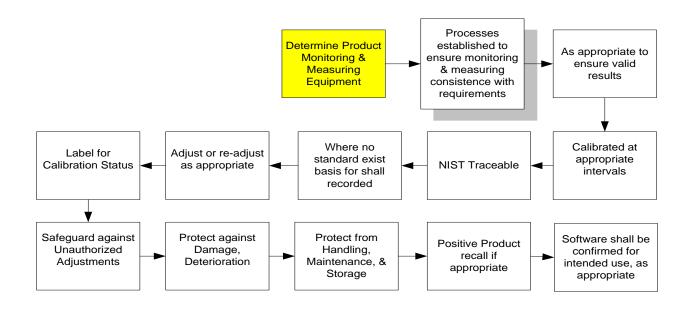
Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
- b) Be adjusted or re-adjusted as necessary;
- c) Have identification in order to determine its calibration status;
- d) Be safeguarded from adjustments that would invalidate the measurement result;
- e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, GTG shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. GTG shall take appropriate action on the equipment and any product affected.

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

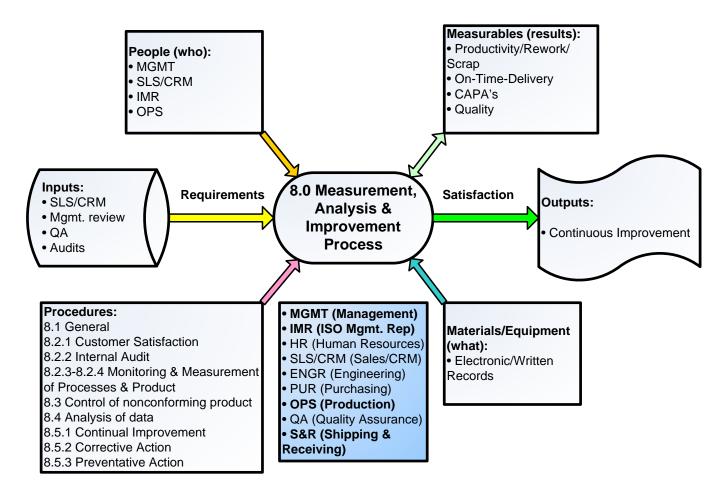
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.



Personal measuring equipment not used for product acceptance shall not be calibrated.

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8.0 Measurement, analysis and improvement



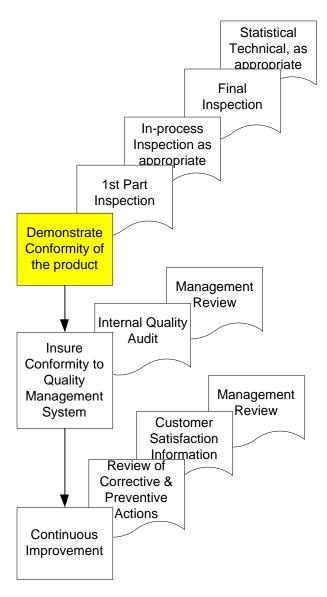
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8.1 General

GTG shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) To demonstrate conformity to product requirements,
- b) To ensure conformity of the quality management system, and
- c) To continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

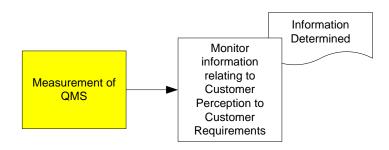


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8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, GTG shall monitor information relating to customer perception as to whether GTG has met customer requirements. The methods for obtaining and using this information shall be determined.



8.2.2 Internal audit

GTG shall conduct internal audits at planned intervals with external service to determine whether the quality management system

- a) Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by GTG, and
- b) Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

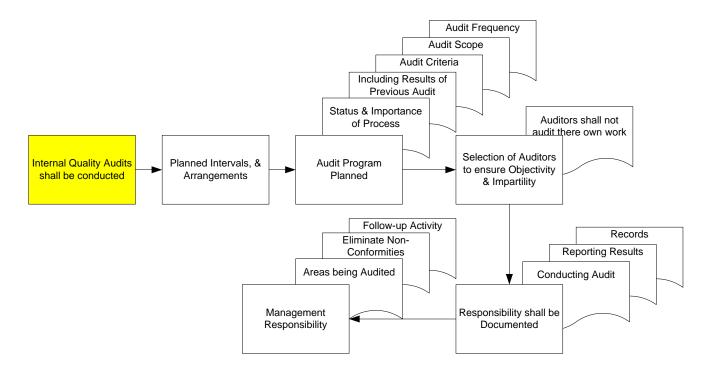
This documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. An Excel Spreadsheet us used to schedule upcoming and completed audits

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

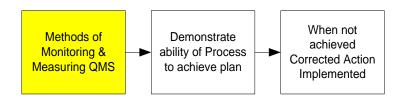
Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

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8.2.3 Monitoring and measurement of processes

GTG shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes such as First Piece Inspection, In-Process Inspection and Final Inspection. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.



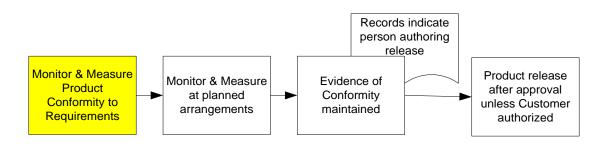
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8.2.4 Monitoring and measurement of product

GTG shall monitor and measure the characteristics of the product using either 100% Inspection or sampling based on C=0, to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.



8.3 Control of nonconforming product

GTG shall ensure that product which does not conform to product requirements is identified and controlled using a Discrepant Material Report and/or Quality Tags, to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

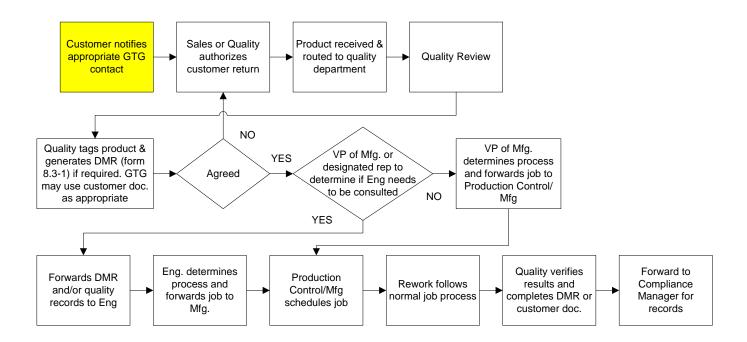
Where applicable, GTG shall deal with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity;
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) By taking action to preclude its original intended use or application;
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

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

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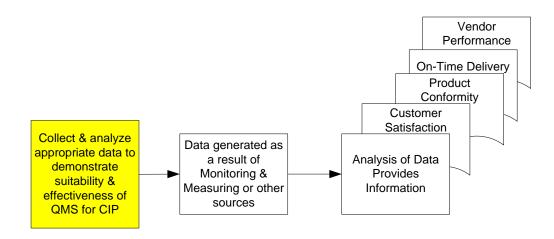
8.4 Analysis of data

GTG shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) Customer satisfaction (see 8.2.1),
- b) Conformity to product requirements (see 8.2.4),
- c) Characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) On-Time Delivery
- e) Supplier Performance

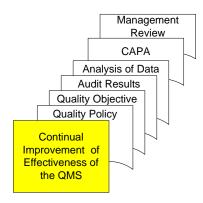
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8.5 Improvement

8.5.1 Continual improvement

GTG shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.



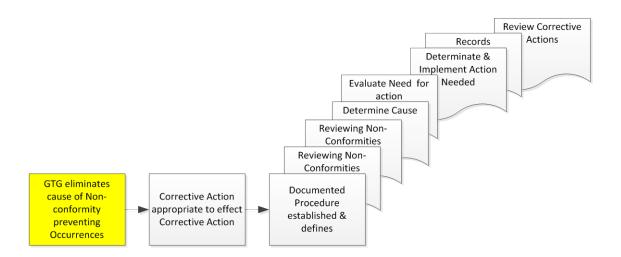
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8.5.2 Corrective action

GTG shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of action taken (see 4.2.4), and
- f) Reviewing the effectiveness of the corrective action taken.



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8.5.3 Preventive action

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

A documented procedure shall be established to define requirements for

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Records of results of action taken (see 4.2.4), and
- e) Reviewing the effectiveness of the preventive action taken.

