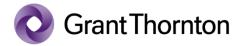


Quality Management System

According to ISO 9001:2015 requirements

[The Quality Manual describes Grant Thornton's Quality Management System, defines processes, authorities, interrelationships and responsibilities of the personnel responsible for performing within the system. The manual also provides references for all activities comprising the QMS to ensure compliance to the necessary requirements of the ISO standard. The particular manual should be used in conjunction with AQCM, TSM, ASM and AASM]





This document is issued, approved, revised, and distributed according to Grant Thornton relevant procedures for document control.

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- 1. Is not marked as "NOT VALID", "DRAFT" or "FOR INFORMATION"
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1 Scope

1.1 General

The aim of this manual is to:

- Describe the Grant Thornton's Quality Management System concisely
- Demonstrate the implemented Management System's conformity with the requirements of the ISO 9001:2015 standard. From the identification of the customer needs and expectations, via all the activities of the Quality Management System to the achievement of the customer satisfaction

1.2 Application field

What is included in this Manual is applied to all Grant Thornton's activities related to the:

Provision of Service Lines and Industries

Service Lines:

- Assurance which includes, Statutory Audits, Tax audits, Other Assurance services
- Tax and Outsourcing which is a Subsidiary of Grant Thornton SA which includes provision of tax, accounting and advisory services such as Operational, Transactional, Forensic, Business Risk Services, CSR, Strategy & Investments, Forensic services. Provision of integrated IT solutions.

Industries:

- Financial sector services
- Energy Sector services

The application of what is stated in the present document is obligatory for all Grant Thornton's personnel. Moreover, the present is validated and approved by the Board of Directors of Grant Thornton.

1.3 Distribution

The Manual shall / can be distributed to:

- A. The Grant Thornton's managers, who are authorized to implement the System throughout their range of responsibility.
- B. Customers, third party auditors and the rest of the external collaborators, in order to inform them about the Grant Thornton's Integrated Management System.

The distribution of this Manual or notification partly or in its entirety, does not create a contractual obligation for the company or its external recipients, unless it is formally agreed and also in the extent that this is agreed.

1.4 Exclusions from the Standard

Requirement § 7.1.5 Monitoring & measuring resources is excluded due to the fact that Grant Thornton doesn't use any equipment for the monitoring and measurement of the services provided.

2. Grant Thornton Greece

2.1 Grant Thornton SA

Legal Structure

Grant Thornton S.A. («Grant Thornton») was established in 1994. Its legal structure is that of Societe Anonyme and its full name is «Grant Thornton S.A. Chartered Accountants and Management Consultants», with its head office located in Palaio Faliro, Athens. Also the Advisory and Industries offices are located in Leof. Syggrou.

Grant Thornton is a member firm of Grant Thornton International Ltd and registered in the Institute of Certified Public Accountants of Greece (SOEL) -under Reg. Number 127 and in the Public Company Accounting Oversight Board (PCAOB) from May 16th 2006. The PCAOB is a non-profit corporation, created by the Sarbanes-Oxley Act of 2002 to oversee the auditors of public companies in order to protect investors and the public interest. The registration with the PCAOB accredits Grant Thornton Greece to carry out audits for companies listed on the US stock ex-change.

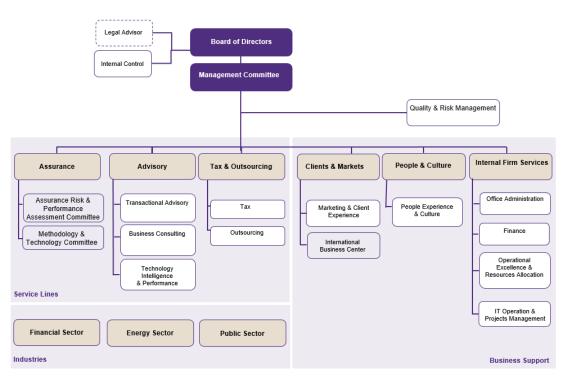




Figure 1: Group Organization Chart

2.2 Grant Thornton Tax & Outsourcing SA

Legal Structure

In 2012 GT Tax and Outsourcing S.A. («Grant Thornton Tax») was established as a subsidiary to Grant Thornton SA. Its legal structure is that of Societe Anonyme, with its head office located in Palaio Faliro, Athens and its scope is the provision of tax and outsourcing services.

Tax and Outsourcing SA is supervised by the Parent company in Quality and Risk Matters and Support services (Clients and Markets & Internal Firm Services).

Subsidiary Organization chart

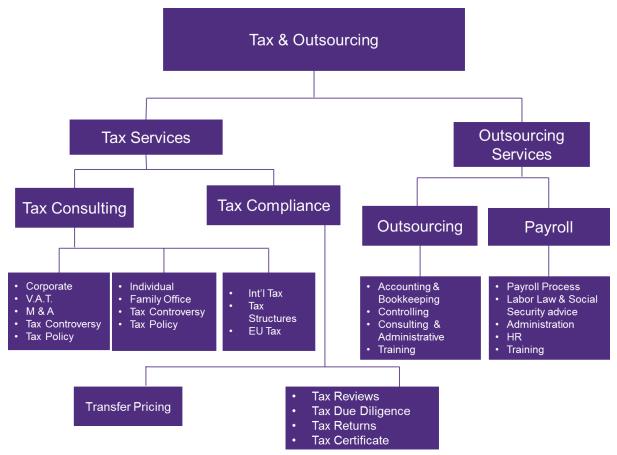


Figure 2: Subsidiary Organization Chart

3. Quality Policy

The Grant Thornton's Quality Policy concerning the provision of the service lines, Assurance, Advisory Services as well as Tax and Outsourcing aims to describe the way Grant Thornton continuously achieves to:

- · correspond to the market's and customers' Quality requirements
- correspond to obligations towards the personnel, the service providers and the society

Quality to us the Grant Thornton's personnel in total means that our activities conform with:

- our customers' requirements & contractual obligations
- our Quality objectives and targets

In order to be consistent with all of the above statements, Grant Thornton:

- A. Has established and implemented a Quality Management System according to the International Standard ISO 9001:2015, related to all activities affecting our customer's satisfaction.
- B. Has set a strong commitment that the company will satisfy applicable statutory and legal requirements.
- C. Continuously reviews and improves the processes effectiveness and therefore the whole Management System
- D. Sets challenging objectives and targets for Quality improvement, which are being evaluated as of their degree of achievement, in the frame of Management Review. More specifically, our objectives are:
 - a. Continual improvement of our business performance
 - b. Maximum customer satisfaction
 - c. Continual improvement of our company image
 - d. Maximization of employee satisfaction
- e. Continual development and training of employees related to the management system E. Provides the required resources for unhindered, effective and efficient operation of each
- E. Provides the required resources for unnindered, effective and efficient operation of each department
- F. Invests in the continuous training, education and development of employees, so that they promote Quality in every activity
- G. Identifies, measures, analyzes and evaluates the critical process parameters, that are essential for the achievement of the improvement objectives and targets
- H. Supports both internal and external communication (with customers, service providers and other interested parties) over topics of the management of quality
- I. Is committed that It will continuously improve the performance related to Quality System effectiveness regarding customer satisfaction

Adopting the dynamics of continual improvement, we recognize and reward both team and individual efforts, respecting the employee and the customer.

Implementing the principles of Quality, the company top management is committed to consistent conformity with the above statements. The Policy will be communicated in order that it is well known by all employees.

Grant Thornton CEO

4. Context of the Organization

4.1 Understanding the company and its contexts

The company shall determine external and internal issues relevant to its purpose and ability to achieve the goals of the Quality System. Relevant issues will be monitored and updated by the company in accordance with the QMS.

4.2 Understanding the needs and expectations of interested parties

Grant Thornton shall determine interested parties that are relevant to the Quality Management System, and the requirements of these parties. Grant Thornton shall monitor and review information about these parties and their requirements. Additional information about these procedures is detailed throughout this manual.

In defining internal and external issues Grant Thornton focus on issues that can affect the customer satisfaction and delivery of quality services.

The organization's internal context is the environment in which it aims to achieve its objectives. Internal context can include its approach to governance, its contractual relationships with customers, and its interested parties. Things that are related to the culture, beliefs, values, or principles inside the organization, as well as complexity of processes and organizational structure.

To determine external context, you should consider issues arising from its social, technological, environmental, ethical, political, legal, and economic environment. External and internal issues give rise to risks and opportunities that need to be identified and managed through the Quality Management System.

Our organization is committed to defining our position in the market place and understanding how relevant factors arising from legal, political, social and technological issues influence our strategic direction and our organizational context.

Grant Thornton identifies, analyses, monitors and reviews factors that may affect our ability to satisfy our customers and shareholders as well as; factors that may adversely affect the stability of our process, or our management system's integrity.

External issues for Grant Thornton include:

- Government regulations and potential changes of local law and national government
- Economic shifts in the organization's market
- Organization's competition
- Events that may affect corporate image
- Changes in technology
- Corporate social responsibility
- Customers & external providers
- Cultural & social environment

Internal issues for Grant Thornton include:

- Values and culture
- Market share
- Employees training and development performance
- Professional growth
- Assets and equipment
- Innovation & knowledge
- Confidentiality and data protection
- Corporate social responsibility
- Service lines capabilities

The interested parties that are relevant to the Quality Management System are as follows:

- Shareholders (invest in company, earn dividends form profits, participate in decision making)
- **Clients** (Choose and trust the company for its services provided, the company is rewarded with revenues for the quality of services provided)
- **Employees** (Offer their work and knowledge, rewarded with salaries, benefits and opportunities for professional and personal development)
- **External providers** (They provide services & products to the company and receive payment, the company supports local suppliers whenever possible)
- **Community** (The company operates in various communities, the company produces social product through local aid agencies, voluntary actions and pro bono services)
- Mass media (Communicate the services and actions of the company, positive publicity)
- **Government & Institutions** (The state provides a regulatory framework for operation. Protects and creates the condition for doing business, receives taxes and social product from company's operation.
- **Grant Thornton International** (The network has developed policies and procedures in accordance of effective professional standards, regulations and laws that the company has also established).
- ELTE (HAASOB) and SOEL (regulatory bodies that supervise the company)
- PCAOB (regulatory body)

4.3 Determining the scope of the Quality Management System

As set on par. 3 Quality Policy.

4.4 Quality Management System and its processes

Grant Thornton has stablished a QMS to achieve the company's policy, ensure service quality and promote continuous improvement. The QMS has been instituted in accordance of ISO 9001:2015 and is comprised of:

- Quality policy and Objectives
- Assurance and Quality Manual Control (AQCM)
- Tax & Outsourcing Services Manual (TSM)
- Advisory Services Manual (ASM)
- Operating Procedures which define major processes including process owners, responsibilities and authorities, inputs and outputs, risks and opportunities, critical and supporting resources, effectiveness of processes.

The company will maintain documented information to support the operation of its processes and that are being carried out as planned (work instructions for specific tasks, Appraisals employee training programs, resource allocation system, training programs, performance measurement, internal auditing, Management Review, Corrective and Preventive actions).



5 Leadership

5.1 Leadership and Commitment

General



Top Management establish unity of purpose and direction of the organization. They should create and maintain the environment in which people can become fully involved in achieving the organization's objectives. In respect to quality top management shall demonstrate leadership and commitment by promoting the use of process approach and risk – based thinking.

Key benefits:

• People will understand and be motivated towards the organization's goals and objectives.

• Activities are evaluated, aligned and implemented in a unified way.

- Miscommunication between levels of an organization will be minimized.
- Ensuring that the quality management system achieves its intended results.

Top management provides the leadership and governance to all activities related to the lifecycle processes including defining the strategic direction, responsibility, authority and communication to assure effective performance. Grant Thornton senior management is committed to implementing and developing the quality management system and this commitment is defined by our corporate policies and objectives. The organization ensures that our policies are understood, implemented, maintained throughout at all levels of the organization through printed distribution of our policy statements and corporate level improvements objectives. The organization communicates our mission, vision, strategy, policies and processes to all employees who form an integral part of Grant Thornton' strategic plans to grow market share, service lines capability, profitability and value.

Applying the principle of leadership typically leads to:

- Creating and sustaining shared values of fairness and ethical behavior
- Encouraging commitment to quality
- Considering the needs of all interested parties including customers, owners, employees, service providers, financiers, local communities and society as a whole
- Establishing a clear vision of the organization's future
- Setting challenging goals and targets
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization



- Establishing trust and eliminating fear
- Providing people with the required resources, training and freedom to act with responsibility and accountability
- Inspiring, encouraging and recognizing people's contribution
- Promoting improvement

Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations. Also senior management is also committed to the achievement to the achievement of customer satisfaction addressing risks and opportunities that affect service conformance, regulatory or statutory requirements.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.
- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, service providers, financiers, local communities and society as a whole).

5.2 Policy

Establishing the quality policy

An overall Quality Policy articulating senior management's commitment to quality has been approved by Grant Thornton's CEO. This policy is stated in par. 3 Quality Policy.

Communicating the quality policy

The Quality Policy shall be:

- Available and maintained as documented information
- Communicated, understood and applied within the organization
- Available to relevant interested parties through Transparency report/client's proposals

5.3 Organizational roles, responsibilities and authorities

Senior management has assigned responsibilities and authorities to all relevant roles in the company.

A Quality Assurance Manager has been appointed with full responsibility and authority for all matters pertaining to quality and Quality Management System, including:

- Conformance of this Quality Manual
- Reporting performance of the Quality Management System and opportunities for improvement to senior management
- Ensuring promotion of customer focus throughout the organization.

• Ensuring that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

Motivated, committed and involved people within the organization.

- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.
- Applying the principle of involvement of people typically leads to:
- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and the responsibility of solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues

6 Planning for the Quality Management System

6.1 Actions to address risks and opportunities

When planning for the quality management system, the organization shall consider the issues referred to 4.1 and the requirements of interested parties referred to in 4.2 and determined the risks and opportunities that need to be addressed.

Grant Thornton considers risks and opportunities when taking actions within the taking actions within the QMS, as well as when implementing the system; likewise these are considered relative services.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of services, in order to:

- 1. Give assurance that the QMS can achieve its intended results,
- 2. Enhance desirable effects
- 3. Prevent, or reduce undesired effects
- 4. Achieve improvement

The company shall plan:

- A. Actions to address risks and opportunities and
- B. How to



- C. Intergrade and implement the actions into its quality management processes
- D. Evaluate the effectiveness of these actions

6.2 Quality objectives and planning to achieve them

Grant Thornton establishes quality objectives at relevant functions, levels and processes as the main quality objectives for the Quality Management System. The Quality objectives shall:

- a. Be consistent with the quality policy;
- b. Be measurable;
- c. Take into account applicable requirements;
- d. Be relevant to conformity of services and to enhancement of customer satisfaction;
- e. Be monitored;
- f. Be communicated;
- g. Be updated as appropriate;

The company shall maintain documented information on the quality objectives.

6.3 Planning of changes

Planning is performed before changes to the Quality Management System are implemented, to ensure quality objective achievement and system integrity.

When Grant Thornton determines changes to the Quality Management System to be necessary, the company shall consider:

- a. The purpose of the changes
- b. The integrity of the Quality Management System
- c. The availability of resources
- d. The allocation or reallocation of responsibilities and authorities

7 Support

7.1 Resources

General

In order to achieve quality objectives, Grant Thornton' s senior management determines the capabilities necessary, human and physical resources and needs to be obtained from external and internal providers. Specific resource requirements are analysed and assigned during Management reviews. Customer satisfaction is enhanced by meeting customer expectations.

People

The Organization shall determine and provide the persons necessary for the effective implementation of its quality management System and for the operation and control its processes.

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

Applying the principle of involvement of people typically leads to:



- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and the responsibility of solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues

Infrastructure

The Organization determines, provides and maintains the infrastructure necessary including facilities and resources, utilities, employee workspace and support services for the operation of its processes and to achieve conformity of services.



Environment for the operation process

In order to achieve quality objectives, Grant Thornton senior management determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of services.

Environmental issues considered include lighting, heating and air conditioning, cleanliness, health and safety and business ethics. Company environment for the operation of processes is assessed during planned Internal Audits.

Monitoring and measuring resources

N/A

Organizational Knowledge

Grant Thornton determines the knowledge necessary for the operation of its processes and to achieve conformity of services. This knowledge shall be maintained and made available as necessary:

- a. Knowledge may be obtained from internal sources, Grant Thornton International policies and prior experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience, results of improvements in processes.
- b. External sources such as standards, conferences, academia, knowledge from clients and external providers.

7.2 Competence

Grant Thornton has stablished methods for competency, quality awareness development, training provision and evaluation appraisals. Records of employee education, skills, training and experience are maintained by People Experience & Culture Department.

7.3 Awareness

Grant Thornton ensures that employees are aware of the Quality Policy, quality objectives, their contribution to the effectiveness of the management System (including benefits of improved performance) and implications of not conforming to the Quality Management System requirements.

7.4 Communication

Effective and appropriate communications between functions and levels regarding QMS effectiveness are promoted by senior management.

Communication may be initiated by any employee and by senior management through regular meetings. Communication may include:

- Firms events (Growth awards)
- Internal Communication (Newsletters, Alerts & email communication, growth point, mailbox, CSR, Yammer, SharePoint)
- Corrective of Preventive Actions
- Meetings (Partners meetings, Management Committee meetings, annual events)
- Focus groups
- Events and excursions for networking & team building
- Internal audit results
- Data analysis
- Memos

7.5 Documented information

General

The Quality Management System shall include all documented information required by ISO 9001:2015 and determined by Grant Thornton to be necessary to the effectiveness of the Quality Management System. The extent of the Quality Management System is based upon the following:

- a. The size of Grant Thornton
- b. Complexity and interaction of its processes
- c. Risks and Opportunities
- d. Competence of personnel



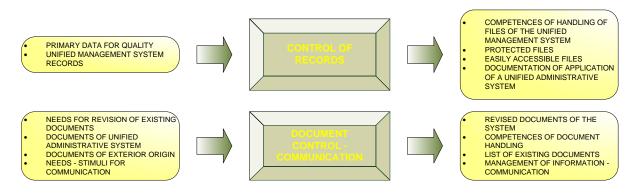
Creating and Updating

When creating and updating documented information, Grant Thornton shall ensure appropriate:

- Review and approval of documents for adequacy prior to initial release
- · Periodic review, update and re-approval of existing documents as required
- Clear document identification, format, revision indication and current revision status

Control of documented information

All documents comprising the Quality Management System are monitored (SOP – Control Of records. SOP-4 Document control)



Control measures

Control measures include:

- Availability of current and relevant documents at all locations where quality related activities are performed
- Protected from loss of confidentiality, improper use or loss of integrity
- Obsolete documents are removed from points of use and protected from unintentional use

Quality records maintenance

Quality records are maintained to demonstrate conformance to specified requirements and include:

- Controlled distribution, access, retrieval and use
- · Periodic audits to confirm documents, presence and legibility
- Storage and presentation, including preservation of legibility
- Control of changes
- Retention and disposal

Documented information retained as evidence of conformity shall be protected from unintended alterations.

8 Operation

A process is a set of activities that are interrelated or interact with one another and use resources to transform inputs into outputs. The recognized processes are classified in four categories:

- Management Processes
- Assessment Processes
- Support Processes
- Measurement-Analysis-Improvement Processes, and
- Main operating Processes

8.1 Operational Planning and control

The organization shall plan, implement and control processes needed to meet the requirements for the provision of services and to implement the actions determined by:

- a. Determining the requirements for the services
- b. Establishing criteria for:
 - The processes
 - The acceptance of services
- Determining the resources needed to achieve conformity to the product and service requirements
- d. Implementing control of the processes in accordance with the criteria
- e. Determining, maintaining and retaining documented information to the extent necessary

The output of this planning shall be suitable for the organization's operations.

8.2 Requirements for services

Customer communication

Customer communications with regards to proposals, RFP, and engagement amendments are defined through specific templates and include:

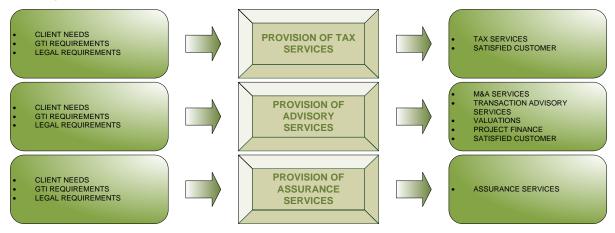
- Providing information relating to services for all service lines
- Handling inquiries, contracts including changes
- Obtaining customer feedback relating to services, including complaints
- Establishing specific requirements for contingency actions



Determining the requirements for services

Prior to generation of a client's proposal, Grant Thornton has set the procedures to meet the requirements of services to be offered.

Following Grant Thornton's provision of services:



Review of the requirements for services

The company has established committees (RMC, AML) that conduct a review to proposals before committing to provide services to a client. Also RMC's Legal Dpt (incorporated within RMC) further reviews specific legal terms on engagement letters/proposals. For NAS (non audit services) to audit clients relevant approval should be obtained from the audit engagement partner.

Changes to requirements for services

The company has established committees (M&T) to ensure that where requirements for services are changed relevant persons are aware of the changed requirements.

8.3 Design and development

Purpose, scope and users

The purpose of this procedure is to describe the design control of software development process during the design and development of its software products to provide evidence of conformity to the requirements specified by ISO 9001:2015, customer requirements and of the effective operation of our management system. Standard forms are used and templates accessed via a local area network computer system.

This procedure applies to software development documentation and is to be followed by all personnel involved in software development.

Software production process

Forming Preliminary design

According to the customer's request or determined needs of the market, a new project is created and the Project Manager, based on initial collection of requirements, defines the preliminary design of

software, designates design team and design team leader, development and quality assurance teams and defines their duties and responsibilities.

Software production planning

Planning software production stages and activities

Project Manager plans stages and controls for the software production process, by taking into account:

- Nature and complexity of the software production activities
- The required stages, including applicable reviews
- The required verification and validation activities
- Internal and external resources needed for software production
- The need to control interfaces between persons involved in the design and development process
- The requirement for subsequent provision of products and services

Authorities and responsibilities in software production

The Project Manager is responsible for:

- Contacting with the customer and collecting the operational requirements
- Generating the Solution Design Document (SDD) or Business Requirements Document (BRD)
- Generating the Project Plan & Review Document (PPRD)
- Making sure that the project has all the required resources (workforce, skills, infrastructure, tools)
- Coordinating any arranging and cooperation between the different groups involved in software development and the customer, suppliers, or other company departments or third parties
- Organizing Phase Review Meetings after completion of significant phases and keeping Phase Review Minutes.
- Organizing kick-off, periodic Progress Review Meetings with the customer and keeping Progress Review Minutes
- Monitoring the timely execution of the workplan, phases, meeting of milestones and delivery of Deliverables
- Preparing and delivering to the customer periodic status reports
- Obtaining top management or customer approval for any additional resources and/or funding

The design team is responsible for:

- Implementing design control
- Reviewing changes in software design
- Defining activities of verification and validation for any phase of software production

The design team leader has the following responsibilities:

- Preparing the Technical Specifications Document (TSD) or Functional Requirements Document (FRD), which may be part of Solution Design Document or separate ones.
- Assuring that all requirements are addressed, documented and approved as necessary including the rationale/justification for not performing certain activities
- Approving changes in design
- Conducting Design Review Meetings and keeping Design Review Meeting Minutes
- Resolving conflicting software design inputs
- Maintaining the Design History File (DHF)
- Defining software design phases

• Approving review, verification and validation of every phase

The development team is responsible for:

- Implementing software development
- Correcting bugs and code deficiencies
- Applying changes to the code
- Keeping revisions of the code
- Issuing software releases
- Preparing the documentation of the software (manuals, operating procedures)

The development team leader has the following responsibilities:

- Assuring that software development is performed according to the design and the selected methodology
- Resolving any implementation issues with the design team
- Breaking down the workplan and assigning tasks to the development team
- Monitoring task execution
- Keeping track of tasks, issues and bugs using a Tasks, Issues & Bugs Tracking System
- Assuring that code revision methodology is applied using a Code Revision System
- Approving branch merges and issuance of new releases using a Version & Release Control System
- Maintaining Version Release Record (VRR)

The quality assurance team is responsible for:

 Implementing software tests in various levels (unit, module, application, integrated system) and stages (test environment, staging, production)

The quality assurance team leader has the following responsibilities:

- Preparing the Test Plan Document (TPD)
- Preparing the User Acceptance Testing (UAT) Document
- Assuring that testing is performed according to the test plan
- Approving before releasing of a new software version, meeting of milestone, delivering of deliverables or final product delivery before and after UAT

In simple projects that have low complexity and extend, some of the above roles and meetings can be merged (with the exception of the quality team and quality team leader which must be separate).

Software design inputs

According to the preliminary design, the Project Manager involves customers and users in the analysis and requirements discovery process and creates the Solution Design Document, which contains input data that defines the request for product by including the following:

Functional and performance requirements

The functional specification described in the Solution Design Document by the project manager according to the customer request for product addresses at least the following points:

- The functional and performance requirements of the customer
- The performance objectives, operating conditions, and the requirements for reliability, availability, and maintainability
- The basic technical interface requirements

- Requirements for calculations, tests and development work
- Demanded quality of software and timeframe

Project Manager must list as a reference the documents, database records, and other information and data used to establish the product or service specification in the Design History File.

Technical specifications

The Solution Design Document is analysed by the design team leader who translates the requirements of the customer into specific and detailed technical specifications and includes them in the Technical Specification Document, which depending on the nature of the project can be part of the Solution Design Document, or can be a separate document.

Statuary, regulatory and other requirements

Statutory and regulatory requirements and other normative documents used for software production, testing and operation procedures should be defined in the Technical Specification Document. Whenever possible, International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards and practices should be used.

Information gathered from previous similar projects

The design team leader must take into consideration the previous similar projects in order to prevent recurrent mistakes and to avoid exceeding the budget and time schedule. If such information exists, it is included in Technical Specification Document.

Other requirements important for design and development

Development team leader must define other requirements related to software design, such as internal and external resource needs for software design, requirements for subsequent provision of software maintenance, potential consequences of failure due to the nature of the software, etc.

Developing the Project Plan and Review

According to Solution Design Document and input data for software design, the Project Manager, together with team members, creates the Project Plan and Review Document and defines:

- Software development methodology
- Team members and responsibilities
- Project governance
- Project phases and timeplan
- Project workplan
- Milestones and deliverables
- Changes in phases and approval of changes
- Project phase status (reviewed, validated, verified and completed)
- Start of new phase

The design and development team member responsible for phase execution enters the following into the Project Plan and Review Document workplan:

- All activities related to phase realization
- Input elements of the phase
- Phase milestones & deliverables
- Resources needed

Software production execution

Software production execution is a process comprising of several stages and steps, as outlined in the following diagram:



The Project Manager ensures that all activities of the phase are conducted and all necessary records about the phase are kept.

The design team leader generates the design / technical specifications. Depending on the selected software development methodology, this process can be one-off and completed before the software development starts, or can be done incrementally in parallel with software development in several consecutive phases.

After completion of the partial / complete design and before beginning of software development the design team leader organizes a Design Review Meeting with the teams involved in software production, for presenting the technical specifications. In case of any remarkable issues or problems with the design the design team leader proposes solutions and amends the Technical Specification Document accordingly. The proceedings of the meeting are recorded in the Design Review Minutes and development starts.

The development team implements the software development tasks of the specific phase based on the Technical Specification Document. The development is performed in a dev environment, where all required development and testing tools are readily available.

Splitting, sharing, assignment and monitoring of software development tasks is performed using Jira.

After review and completion of development tasks, the quality assurance team performs tests according to the Test Plan Document.

The test plan is managed using tools like TestLink, whereas testing process execution is also managed through Jira.

Any issues or bugs identified during the testing process are recorded as new tasks in Jira and they are assigned to the development team by the development team leader for resolution and re-testing.

Code generated during software development is kept in the Gitlab repositories of the project and there is full recording of changes and revisions. Committing of code is done using Git and is linked with Jira tasks.

Significant code developments of separate features and functionalities may be performed in separate branches (forks), which are merged in the main branch based on the deliverables of the specific phase and upon decision of the development team leader.

In case that the specific phase includes partial or complete generation of the software, the development team uses Gitlab to prepare a new release incorporating the necessary features. The code is compiled (if applicable), published and after successful testing the release freezes, release notes are added, it gets a new version number, it is recorded in Version Release Record and is delivered.

All versions of the software are kept in Gitlab and are available any time.

The Project Manager conducts a project Phase Review Meeting before completion of significant phases. People included in software production, as well as customers and other relevant interested parties, can participate in the project phase review if the Project Manager finds it appropriate.

If the project phase review reveals problems, the design team leader suggests actions to resolve them and enters them into the Phase Review Minutes form. The effect of the executed action is the subject of the next review.

After phase review, the design and development team leaders approve the start of the new phase by signing the Project Plan and Review.

Design and development controls

Design team leader ensures that design and development results to be achieved are defined, and reviews are conducted to evaluate the ability of the results of design and development to meet requirements.

Verification of design and development process

The design team leader conducts verification during the project Phase Review Meetings and determines whether the output elements address the input elements of the software production process. If the results of the verification are satisfactory, the design team leader signs the appropriate box in the Project Plan and Review.

Validation of design and development process

Validation is a check-up process that determines whether the final product is capable of satisfying the needs of the customer in specified conditions of use.

The design team leader together with the client conducts partial or complete validation during the Project Review Meetings.

The design team leader will take any necessary action on problems during the reviews, or verification and validation activities, and record them in the Project Review Minutes form.

Design and development outputs

After completion of a phase that includes a partial or complete/final release of the product, the Project Manager, together with team members, enters in Design History File additional information, related to deliverables of software, such as:

- Software code
- Software documentation (for final product)

- Information about resource requirements once it's launched (for final product)
- Details about software maintenance (for final product)
- Requirements of subsequent processes for the provision of product and service (for final product)

Development team leader must approve these output elements of software production before acceptance of the software. Output elements must meet input requirements for software design.

Release in production/market

QA team leader, together with the design team leader, organizes software user acceptance testing (UAT). After satisfying UAT results, the design team leader conducts verification in order to determine whether the software complies with all requests defined in the Solution Design Document. If everything is according to the request, then the product is delivered and further activities such as beginning of warranty and/or support period can be initiated.

Design and development of changes

Changes in software design can occur in every phase of design and development as a result of:

- Changes of software specification on customer request
- New or updated legal and regulatory requirements
- Changes in software production processes
- Problems during production
- Demand of market for improved product
- Project review
- Verification activities
- Validation activities

The design team leader must document all changes in the Change Review Record, and review, verify, validate and approve changes before their application, and evaluate influence of changes on other parts of product and delivered product.

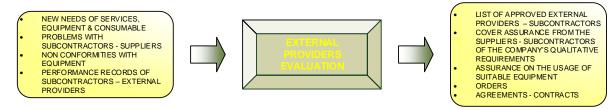
Project review

After completion of all phases of software design, the design team leader conducts a review of software design and delivers Design Review Minutes to the client.

8.4 Control of externally processes and services

General

Grant Thornton ensures that all externally provided processes, products and services conform to specific requirements. The selection criteria and evaluation of external providers is define. Records evaluation performance are maintained.



8.5 Production and service provision

Control of production and services provision

Grant Thornton 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;
- 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.

Identification and traceability

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

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

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

Property belonging to customers or service providers

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

Grant Thornton identifies, verifies, protects and safeguards customer's 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, Grant Thornton reports this to the customer or external provider and retains documented information on what has occurred.

Preservation

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

Post-delivery activities

Grant Thornton meets requirements for post-delivery activities associated with the services.

In determining the extent of post-delivery activities that are required, Grant Thornton 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.

Control of changes

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

Grant Thornton 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 services

Grant Thornton has implemented planned arrangements to verify that service requirements have been met.

The release of services do not proceed until the planned arrangements have been satisfactorily completed and approved by relevant authority.

8.7 Control of non-conforming outputs

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

Grant Thornton 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 the provision of services.

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

- 1. Correction;
- 2. Segregation, containment, return or suspension of provision of products and services;
- 3. Informing the customer; and
- 4. obtaining authorization for acceptance under concession

The following Process Map demonstrates the relationship and interaction between the recognized processes of the Quality Management System:

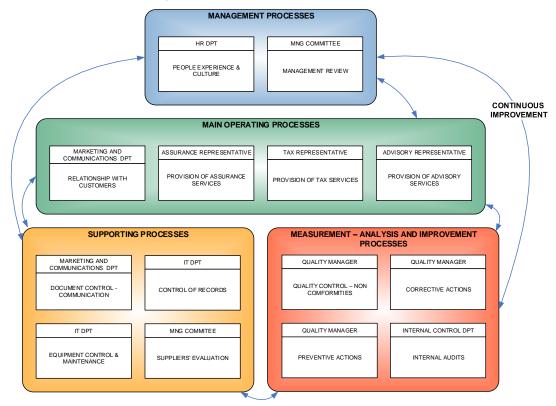


Figure 3: Process Map

9 Performance evaluation

9.1 Monitoring, measurement analysis and evaluation

General

Grant Thornton 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 from monitoring and measurement are analysed and evaluated.

Grant Thornton evaluates the performance and the effectiveness of the quality management system. Grant Thornton retains appropriate documented information as evidence of the results.

Customer satisfaction

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

Analysis and Evaluation

Grant Thornton analyses and evaluates appropriate data and information arising from 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.

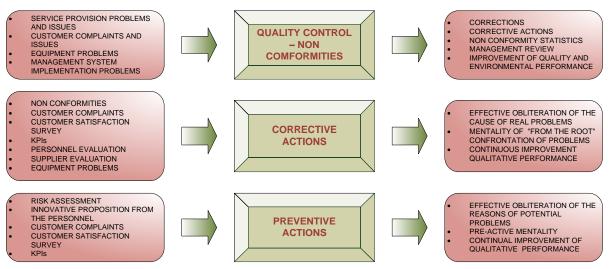
9.2 Internal Audit

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

- a. Conforms to:
- 1. Grant Thornton's own requirements for its quality management system;
- 2. The requirements of ISO 9001:2015 is effectively implemented and maintained.

Grant Thornton has:

- 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 Grant Thornton and the results of previous audits;
- b. Defined the audit criteria and scope of each audit;
- c. Conducted audits to ensure objectively and the impartiality of the audit process through delegated committee;
- 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

General

Top management reviews Grant Thornton's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Grant Thornton.

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 services;
 - 4. Non conformities 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; and
- f. Opportunities for improvement

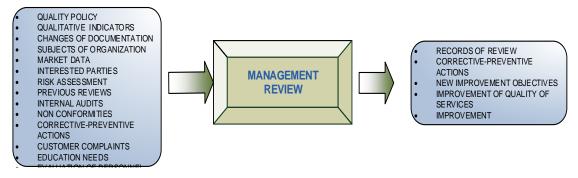
Management Review Outputs

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.

Grant Thornton retains documented information as evidence of the results of management reviews.

In diagram management review inputs & outputs:



10 Improvement

10.1 General

Grant Thornton 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 Non conformity & corrective action

When a nonconformity occurs, including any arising from complaints, Grant Thornton:

- a. Reacts to the non-conformity 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 non-conformity;
 - 2. Determining the causes of the non-conformity;
 - 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.

g. Makes changes to the quality management system, if necessary. Corrective actions are appropriate to the effects of the nonconformities encountered.

10.3 Continual improvement

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

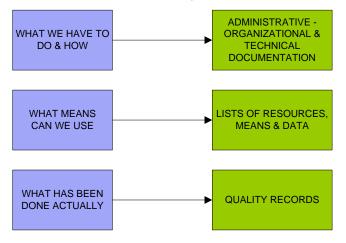
Grant Thornton considers the results of analysis and evaluations, and the outputs from the management review, to determine if there are needs or opportunities that are addressed as part of the continual improvement.

11 Appendix

11.1 QMS Documentation

QMS Structure

The structure of the Quality Management System is based on the flowchart below:



Based on the above diagram and the type of documents that we use, we quote the pyramid of documents of substantiation below:

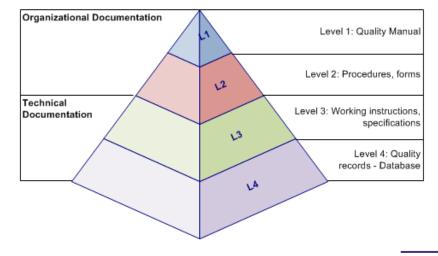


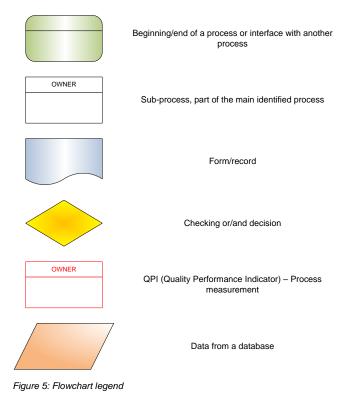
Figure 4: QMS document pyramid

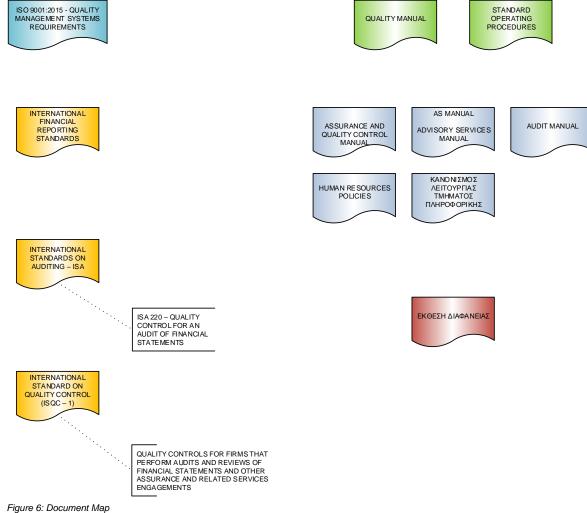
Quality Procedures

| Coding | Title |
|--------|--|
| SOP-01 | Human resources management |
| SOP-02 | Management review |
| SOP-03 | Document control – communication |
| SOP-04 | Control of records |
| SOP-05 | Quality control – Non conformities |
| SOP-06 | Corrective actions |
| SOP-07 | Preventive actions |
| SOP-08 | Internal audits |
| SOP-09 | Service providers evaluation |
| SOP-10 | Resources control and maintenance |
| SOP-11 | Provision of Assurance |
| SOP-12 | Provision of Tax and Outsourcing |
| SOP-13 | Provision of Advisory (updated services) |
| SOP-14 | Relationship with customers |

Table 1: Quality Management System Procedures

In general QMS documented procedures are demonstrated with flowcharts





Integrated Grant Thornton documentation structure

. igure ei 2 courient map

11.2 Definitions – Abbreviations

Definitions

Audit

An audit is an evidence gathering process. Audit evidence is used to evaluate how well audit criteria are being met. Audits must be objective, impartial, and independent, and the audit process must be both systematic and documented.

There are three types of audits: first-party, second-party, and third-party audits. First-party audits are internal audits. Second and third party audits are external audits.

Organizations use first party (internal) audits to audit themselves for internal purposes. However, you don't have to do them yourself. You can ask an external organization to carry out an internal audit on behalf of your organization. You can also use first party audits to declare that your organization complies with the ISO 9001 standard (a self-declaration).

Second party audits are external audits. They're usually done by customers or by others on their behalf. However, they can also be done by any external party that has an interest in your organization.

Third party audits are external audits as well. However, they're performed by independent (disinterested) external organizations. Third party audits are used to determine whether or not an organization complies with the ISO 9001 standard. Third party auditors are referred to as registrars or certification bodies.

Audit criteria

Audit criteria include policies, procedures, and requirements. Audit evidence is used to determine how well such audit criteria are being met. Audit evidence is used to determine how well policies are being implemented, how well procedures are being applied, and how well requirements are being met.

Auditee

An auditee is an organization that is being audited. Organizations include companies, corporations, enterprises, firms, charities, associations, and institutions (or some combination of these). Organizations can be either incorporated or unincorporated and can be privately or publicly owned.

Audit evidence

Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, procedures, and requirements.

Audit evidence can be either qualitative or quantitative. Objective evidence is data that shows or proves that something exists or is true.

Audit findings

Audit findings result from a process that evaluates audit evidence and compares it against audit criteria. Audit findings can show that audit criteria are being met (conformity) or that they are not being met (nonconformity). They can also identify improvement opportunities. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement.

Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used. Audit criteria include policies, procedures, and requirements.

Auditor

In the context of this quality management standard, an auditor is a person who collects evidence in order to evaluate how well quality management systems meet requirements.

Auditors are expected to determine whether quality management systems comply with standards and other planned arrangements. They must also be able to determine whether quality management systems are properly implemented and maintained. And they must be able to do all of this while being independent, objective, impartial, and competent.

Audit plan

An audit plan specifies how you intend to conduct a particular audit. It describes the activities you intend to carry out and the arrangements you intend to make.

An audit is an evidence gathering process. Audit evidence is used to evaluate how well audit criteria are being met.

Audit scope

The scope of an audit is a statement that specifies the focus, extent, and boundary of a particular audit. The scope of an audit is generally defined by specifying the physical location of the audit, the organizational units that will be examined, the processes and activities that will be included, and the time period that will be covered.

Characteristic

A characteristic is a distinctive feature or property of something. Characteristics can be inherent or assigned. An inherent characteristic exists in something or is a permanent feature of something, while an assigned characteristic is a feature that is attributed or attached to something.

Concession

A concession is a special approval that is granted to release a nonconforming product for use or delivery. Concessions are usually limited by time and quantity and tend to specify that nonconforming characteristics may not violate specified limits.

Conformity

In the context of this standard, to conform means to meet or comply to requirements. There are many types of requirements. There are quality requirements, customer requirements, product requirements, management requirements, legal requirements, and so on.

Requirements can be explicitly specified (like the ISO 9001 requirements) or implied. A specified requirement is one that has been stated (in a document, for example). When your organization meets a requirement, you can say that it conforms to that requirement.

Continual improvement

Continual improvement is a set of activities that an organization periodically carries out in order to enhance its ability to meet requirements. Continual improvements can be achieved by carrying out audits (and using audit findings and conclusions), performing management reviews, analyzing data, setting objectives, and implementing corrective and preventive actions.

Correction

A correction is any action that is taken to eliminate nonconformity. However, corrections do not address causes. When applied to products, corrections can include reworking products, reprocessing them, regarding them, assigning them to a different use, or simply destroying them.

Corrective action

Corrective actions are steps that are taken to remove the causes of an existing nonconformity or undesirable situation. The corrective action process is designed to prevent the recurrence of nonconformities or undesirable situations. It tries to make sure that existing nonconformities and situations don't happen again. It tries to prevent recurrence by eliminating causes. Corrective actions address actual problems. Because of this, the corrective action process can be thought of as a problem solving process.

Customer

A customer is anyone who receives products or services from a supplier organization. Customers can be people or organizations and can be either external or internal to the supplier organization. For example, a factory may supply products or services to another industry (customer) within the same organization. According to ISO 9001, examples of customers include clients, consumers, end-users, purchasers, retailers, and beneficiaries.

Customer satisfaction

Customer satisfaction is a perception. It is also a question of degree. It can vary from high satisfaction to low satisfaction. If customers believe that you've met their requirements, they experience high satisfaction. If they believe that you've not met their requirements, they experience low satisfaction.

Since satisfaction is a perception, customers may not be satisfied even though you' ve met all contractual requirements. Just because you haven't received any complaints doesn't mean that customers are satisfied.

There are many ways to monitor and measure customer satisfaction. You can use customer satisfaction and opinion surveys; you can collect product quality data (post-delivery), track warranty claims, examine dealer reports, study customer compliments and criticisms, and analyze lost business opportunities.

Design and development

Design and development is a process (or a set of processes). This process uses resources to transform requirements (inputs) into characteristics or specifications (outputs) for products, processes, and systems.

You may treat design and development as different stages of a single integrated design and development process or you may treat design and development as two (or more) separate processes. You may also use the terms design and development interchangeably if they mean the same thing in your organization. Design and development review

Design and development review is a set of activities whose purpose is to evaluate the suitability, adequacy, effectiveness, and sometimes the efficiency of a set of characteristics or specifications. Design and development review can be used to evaluate product, process, and system characteristics or specifications. In this context, an effective set of characteristics or specifications is one that has the potential to achieve planned results or realize planned activities. Design and development validation

Design and development validation is a process. This process uses objective evidence to confirm that products meet the requirements which define their intended use or application. Whenever specified requirements have been met, a validated status is achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment. Design and development verification

Design and development verification is a process. It uses objective evidence to confirm that design and development outputs meet design and development input requirements. Whenever specified input requirements have been met, a verified status is achieved. Effectiveness

Effectiveness refers to the degree to which a planned effect is achieved. Planned activities are effective if these activities are realized. Similarly, planned results are effective if these results are actually achieved.

For example, an effective process is one that realizes planned activities and achieves planned results. Similarly, an effective set of characteristics or specifications is one that has the potential to realize planned activities and achieve planned results Efficiency

Efficiency is a relationship between results achieved (outputs) and resources used (inputs). Efficiency can be enhanced by achieving more with the same or fewer resources. The efficiency of a process or system can be enhanced by achieving more or getting better results (outputs) with the same or fewer resources (inputs).

Infrastructure

The term infrastructure refers to the entire system of facilities, resources, and services that an organization needs in order to function. According to ISO 9001, Part 7.1.3, the term infrastructure includes buildings and workspaces (including related utilities), process resources (both hardware and software), support services (such as transportation and communications), and information systems.

Inspection

Inspections use observation, measurement, testing and judgment to evaluate conformity. Inspection results are compared with specified requirements in order to establish whether conformity has been achieved. Product inspections compare product characteristics with product requirements in order to evaluate conformity.

Interested party

An interested party is a person or group that has a stake in the success or performance of another organization. Interested parties may be directly affected by the organization or actively concerned about its performance. Interested parties can come from inside or outside of the organization. Examples of interested parties can include customers, service providers, owners, partners, employees, unions, bankers, or members of the general public.

Internal audit

Internal audits are referred to as first-party audits. Organizations use internal (first party) audits to audit themselves for internal purposes. However, you don't have to do them yourself. You can ask an external organization to carry out an internal audit on behalf of your organization. You can use first party audits to declare that your organization complies with the ISO 9001 standard. This is called a self-declaration.

Management

The term management refers to all the activities that are used to coordinate, direct, and control an organization. In this context, the term management does not refer to people. It refers to activities. ISO 9001 uses the term top management to refer to people.

Management review

The overall purpose of a management review is to evaluate the suitability, adequacy, and effectiveness of an organization's quality management system, and to look for improvement opportunities.

Management reviews are also used to identify and assess opportunities to change an organization's quality policy and quality objectives, to address resource needs, and to look for opportunities to improve its products.

Management system

A management system is a set of interrelated or interacting elements that organizations use to implement policy and achieve objectives.

There are many types of management systems. Some of these include quality management systems, environmental management systems, emergency management systems, food safety management systems, occupational health and safety management systems, information security management systems, and business continuity management systems.

Measuring resources

In the context of this standard, measuring resources includes all the things that are needed to carry out a measurement process. Accordingly, measuring resources includes measuring instruments and apparatuses as well as all the associated software, standards, and reference materials.

Nonconforming product

When one or more characteristics of a product fail to meet specified requirements, it is referred to as a nonconforming product. When a product deviates from specified product requirements, it fails to conform. Nonconformity products must be identified and controlled to prevent unintended use or delivery.

A product is the output of a process. Products can be tangible or intangible. ISO 9001 lists four generic product categories: services, software, hardware, and processed materials.

Non-conformity

Non-conformity refers to a failure to comply with requirements. A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties.

There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, product requirements, and legal requirements. Whenever your organization fails to meet one of these requirements, a nonconformity occurs. ISO 9001 lists quality management system requirements. When your organization deviates from these requirements, a nonconformity occurs.

Objective evidence

Objective evidence is data that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or by using any other suitable method.

Outsourced process

An outsourced process is any process that is part of your organization's quality management system (QMS) but is performed by a party that is external to your organization.

According to ISO 9001, you must identify and control your outsourced processes, and you must ensure that each outsourced process is effective. You also need to figure out how to control the interaction between internal and outsourced processes.

A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs.

According to ISO/TC 176/SC 2/N526R, "the terms subcontract and outsource are interchangeable and have the same meaning".

Preventive action

Preventive actions are steps that are taken to remove the causes of potential nonconformities or potential situations that are undesirable.

The preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist. It tries to prevent occurrence by eliminating causes.

While corrective actions prevent recurrence, preventive actions prevent occurrence. Both types of actions are intended to prevent nonconformities.

Preventive actions address potential problems, ones that haven't yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

Procedure

A procedure is a way of carrying out a process or activity. According to ISO 9001, procedures may or may not be documented. However, in most cases, ISO 9001 expects you to document your procedures.

Documented procedures can be very general or very detailed, or anywhere in between. While a general procedure could take the form of a simple flow diagram, a detailed procedure could be a one page form or it could be several pages of text.

A detailed procedure defines and controls the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which inputs should be used, and what outputs should be generated.

Process

A process is a set of activities that are interrelated or that interact with one another. Processes use resources to transform inputs into outputs. Processes are interconnected because the output from one process becomes the input for another process. In effect, processes are "glued" together by means of such input output relationships.

Organizational processes should be planned and carried out under controlled conditions. An effective process is one that realizes planned activities and achieves planned results.

Process approach

The process approach is a management strategy. When managers use a process approach, it means that they manage the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.

Process-based quality management system (QMS)

A process-based quality management system uses a process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.

Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single integrated process-based QMS.

The concept of a "process-based quality management system" is briefly mentioned in the introduction to ISO 9001 (section 0.2). However, ISO 9001 does not formally define this important term so we've given it a try.

Product

A product is the output of a process. Products can be tangible or intangible. ISO 9001 lists four generic product categories: services, software, hardware, and processed materials. Many products combine several of these categories. For example, an automobile (a product) combines hardware (e.g. tires), software (e.g. engine control algorithms), and processed materials (e.g. lubricants).

Service is always the result of an interaction between a service supplier and a customer and can take many forms. Service can be provided to support an organization's own products (e.g. warranty service or the serving of meals). Conversely, service can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). Service can also involve the provision of an intangible thing to a customer (e.g. entertainment, transportation, or advice). While software is intangible, and includes things like approaches and procedures, hardware and processed materials are tangible and are often referred to as goods.

Product inspection

Product inspection is an activity that compares product characteristics with product requirements in order to evaluate conformity. More precisely, a product inspection compares one or more characteristics of a product with specified requirements in order to determine if the product meets these requirements. Product inspections use observation, measurement, testing and judgment to evaluate conformity.

Product realization

A product starts out as an idea. The idea is realized or actualized by following a set of product realization processes. Product realization refers to all the processes that are used to bring products into being.

Quality

The quality of something can be determined by comparing a set of inherent characteristics with a set of requirements. If those inherent characteristics meet all requirements, high or excellent quality is achieved. If those characteristics do not meet all requirements, a low or poor level of quality is achieved.

Quality is, therefore, a question of degree. As a result, the central quality question is: How well does this set of inherent characteristics comply with this set of requirements? In short, the quality of something depends on a set of inherent characteristics and a set of requirements and how well the former complies with the latter.

According to this definition, quality is a relative concept. By linking quality to requirements, ISO 9001 argues that the quality of something cannot be established in a vacuum. Quality is always relative to a set of requirements.

Quality assurance (QA)

Quality assurance is a set of activities intended to establish confidence that quality requirements will be met. QA is one part of quality management.

Quality characteristic

A quality characteristic is tied to a requirement and is an inherent feature or property of a product, process, or system.

A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. An inherent feature or property exists in something or is a permanent characteristic of something.

Quality control

Quality control is a set of activities intended to ensure that quality requirements are actually being met. Quality control is one part of quality management.

Quality improvement

Quality improvement refers to anything that enhances an organization's ability to meet quality requirements. Quality improvement is one part of quality management.

Quality management

Quality management includes all the activities that organizations use to direct, control, and coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include quality planning, quality control, quality assurance, and quality improvement.

Quality management system (QMS)

A quality management system is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

A process-based QMS uses a process approach to manage and control how its quality policy is implemented and quality objectives are achieved. A process-based QMS is a network of many interrelated and interconnected processes (elements).

Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single process-based QMS.

Quality planning

Quality planning involves setting quality objectives and then specifying the operational processes and resources that will be needed to achieve those objectives. Quality planning is one part of quality management.

Quality plan

A quality plan is a document that is used to specify the procedures and resources that will be needed to carry out a project, perform a process, realize a product, or manage a contract. Quality plans also specify who will do what and when.

Quality policy

An organization's quality policy defines top management's commitment to quality. A quality policy statement should describe an organization's general quality orientation and clarify its basic intentions.

Quality policies should be used to generate quality objectives and should serve as a general framework for action. Quality policies can be based on the ISO 9001 Quality Management Principles and should be consistent with the organization's other policies.

Quality objectives

A quality objective is a quality oriented goal. A quality objective is something you aim for or try to achieve.

Quality objectives are generally based on or derived from your organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.

Record

A record is a type of document. Records provide evidence that activities have been performed or results have been achieved. They always document the past. Records can, for example, be used to show that traceability requirements are being met, that verification is being performed, and that preventive and corrective actions are being carried out.

Requirement

A requirement is a need, expectation, or obligation. It can be stated or implied by an organization, its customers, or other interested parties. A specified requirement is one that has been stated (in a document for example), whereas an implied requirement is a need, expectation, or obligation that is common practice or customary.

There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, product requirements, and legal requirements.

Review

A review is an activity. Its purpose is to figure out how well the thing being reviewed is capable of achieving established objectives. Reviews ask the following question: is the subject of the review a suitable, adequate, effective, and efficient way of achieving your organization's objectives?

There are many kinds of reviews. Some of these include management reviews, design and development reviews, customer requirement reviews, and nonconformity reviews. Relative to the previous types of reviews, the focus of each review is as follows: quality management systems, design characteristics and specifications, customer requirements, and nonconformities, respectively.

Service

According to ISO 9001:2015, a service is a type of product. Service is always the result of an activity or interaction between a service supplier and a customer and can take many forms.

Service can be provided to support an organization's own products (e.g. warranty service or the serving of meals). Conversely, service can be provided for a product supplied by a customer (e.g. a repair service or a delivery service). Service can also involve the provision of an intangible thing to a customer (e.g. entertainment, transportation, or advice).

Special process

A special process is any production or service delivery process that generates outputs that cannot be measured, monitored, or verified until it's too late. It's often too late because deficiencies may not be obvious until after the resulting products have been used or services have been delivered. In order to prevent output deficiencies, these special processes must be validated in order to prove that they can generate planned results.

Standard

A standard is a document. It is a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.

ISO's standards are agreements. ISO refers to them as agreements because its members must agree on content and give formal approval before they are published. ISO standards are developed by technical committees. Members of these committees come from many countries. Therefore, ISO standards tend to have very broad support.

External provider

An external provider is a person or an organization that provides products. Service providers can be either internal or external to the organization. Internal service providers provide products to people within their own organization while external service providers provide products to other organizations. Examples of service providers include organizations and people who produce, distribute, or sell products, provide services, or publish information.

Top management

When ISO 9001 uses the term top management it is referring to a person or a group of people at the highest level within an organization. It refers to the people who coordinate, direct, and control organizations.

The term management refers to all the activities that are used to coordinate, direct, and control an organization. The term management does not refer to people. It refers to activities.

Traceability

Traceability is the ability to identify and trace the history, distribution, location, and application of products, parts, and materials. A traceability system records and follows the trail as products, parts, and materials come from service providers and are processed and ultimately distributed as end products.

Validation

Validation is a process. It uses objective evidence to confirm that the requirements, which define an intended use or application, have been met. Whenever all requirements have been met, a validated status is achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment.

In the context of this standard, the term validation is used in at least two different situations: design and development and production and service provision. Design and development validations use objective evidence to confirm that products meet the requirements which define their intended use or application.

Production and service provision processes must be validated whenever process outputs cannot be measured, monitored, or verified until after the product is in use or the service has been delivered (by then it's too late to do anything about output deficiencies and defects). In this case, validations use objective evidence to confirm that production and service provision processes are capable of producing planned results.

Verification

Verification is a process. It uses objective evidence to confirm that specified requirements have been met. Whenever specified requirements have been met, a verified status is achieved.

In the context of this standard, the term verification is used in at least two different situations: design and development and purchasing. Design and development verifications use objective evidence to confirm that design and development outputs meet specified input requirements. Similarly, objective evidence must be used to verify or confirm that purchased products meet specified purchasing requirements.

There are many ways to verify that requirements have been met. For example, you could do tests, perform demonstrations, carry out alternative calculations, compare a new design specification with a proven design specification, or you could inspect documents before you issue them.

Work environment

The term environment of the operation of processes refers to working conditions. It refers to all of the conditions and factors that influence work. In general, these include physical, social, psychological, and environmental conditions and factors. Environment of the operation of processes includes lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices as well as reward and recognition programs. All of these things influence work.

Abbreviations

| GTIL: | Grant Thornton International Ltd | |
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| Grant Thornton: Grant Thornton S.A and | | |
| | Grant Thornton Tax and Outsourcing S.A. | |
| AQCM: | Assurance & Quality Control Manual | |
| AS: | Advisory Services | |
| TAX: | Tax and accounting services | |
| QMS: | Quality Management System | |
| QM: | Quality Manual | |
| SOP: | Standard Operating Procedure | |



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