



موسسه مهندسی و مدیریت ساخت

علوی پور

Alavipour Construction Engineering and
Management Institute

dralavipour.com

Establishing Project Engineering Office in Construction Projects Session 1



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References

- Ray Tricker - ISO 9001_2015 In Brief-Routledge (2016)
- ISO 9001: 2015 Standard, ISO (2015)
- (Management and Industrial Engineering) Dhanasekharan Natarajan (auth.) - ISO 9001 Quality Management Systems – Springer (2017)

WHO AND WHAT IS ISO?

- In 1946, **25 delegates from 25 different countries** met at the Institute of Civil Engineers in London and decided to create a new international organisation '**to facilitate the international coordination and unification of industrial standards**'. As a result, the **International Standards Organization (ISO)** was established as a United Nations Agency in 1947 and is an independent, non-governmental membership organisation is made up of member bodies from **162** countries with **one standards body** representing each member country (e.g. **BSI** for the United Kingdom and **ANSI** for the United States).

How ISO was established?

Session 1

WHO AND WHAT IS ISO?



ISO founder members, London 1946

WHO AND WHAT IS ISO?

- These representatives make up a number of **Technical Bodies (such as ISO/TC 176 for Quality Management and Quality Assurance)** that are responsible for the development of standards.
- ISO has a Central Secretariat based in **Geneva, Switzerland** and is the world's largest producer of **voluntary international standards** covering almost **all aspects of industry and manufacturing**.



The International Standards Organization logo

WHO AND WHAT IS ISO?

- Because the '**International Organization for Standardization**' would have different acronyms in different languages [**IOS** in **English**, **OIN** in **French** (Organisation internationale de normalisation)], the founders decided to give it the short form '**ISO**' which is derived from the **Greek isos**, meaning **equal**.
- Thus, whatever the country, whatever the language, ISO standards are always **equally applicable** and **equally acceptable**.

BACKGROUND REMINDER

- When ISO 9000 was first released in **1987**, it was recognised as being **largely incomplete** and the auditors were required to fill in **lots of the gaps**.
- The first revision of the ISO 9000 series, in 1994, was a **definite step forward** in the right direction but an organisation could still conform to the standard while at the same time produce substandard products and services - but at least they were of a consistently poor quality!

BACKGROUND REMINDER

- Even though the 1994 edition addressed most of the previous problems with the 1987 standard, by introducing 20 specific – but separate – requirements (e.g. document control, review procedures, customer satisfaction, etc.) for an organisation to prove compliance, meant that **any internal or external audit** was virtually a **‘tick in the box’ exercise**.
- Even more contentious was the problem that some organisations were **not manufacturers** and, therefore, **did not need to** carry out all the 20 elements making up the ISO 9001:1994 standard in order to become a quality certified organisation.

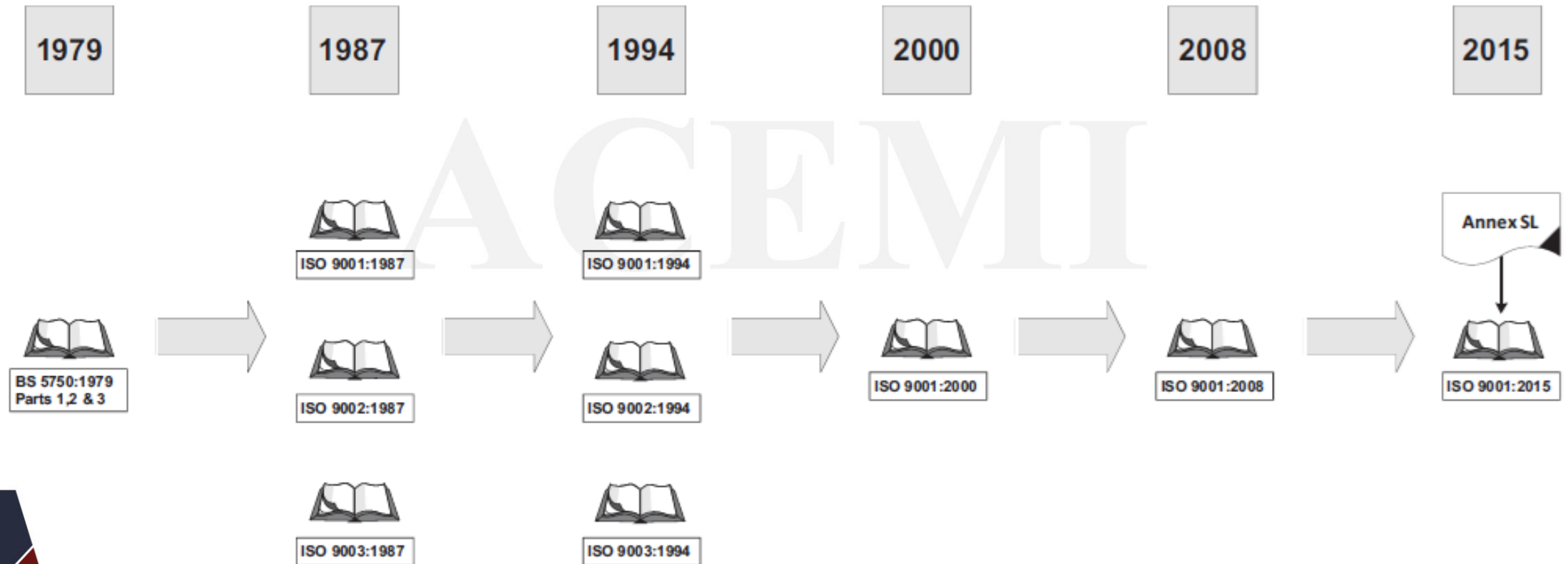
BACKGROUND REMINDER

- It also gave organisations a choice of three 1994 standards (i.e. ISO 9001, ISO 9002 and ISO 9003) to choose from – and the feeling in some corners of the industrial world was ‘**why bother with it all?!**’ There was clearly a need for revision, with the overall aim of making a new ISO 9001 standard that was:
 - more compatible with the other management systems;
 - more closely associated with business processes;
 - easier to understand;
 - capable of being used by all organisations, no matter their size;
 - capable of being used by all types of industry and profession (i.e.manufacturers **and** service providers).

BACKGROUND REMINDER

- These aims were included in the 2000 version of ISO 9001 (which incidentally did away with the three-sector format of the previous 1994 standard and became a combined ISO 9001: 2000), and this new standard was immediately **welcomed by all sectors of business** as a step in the right direction – particularly as it emphasized the need for a **business process format**.
- Following the publication of some minor amendments to ISO 9001 in 2008 and, in accordance with the rules of ISO, all international standards need to be reviewed and revised **every 5 years** and so in 2015 a new version of ISO 9001 standards was published but this time, in accordance with the rules set out in Annex and in a similar format to all future ISO management standards.

The History of ISO



Comparing last versions and Why it is Important?

Structure and terminology:

the clause sequence and some of the terminology have been changed to improve alignment with other management systems standards

ISO 9001:2008	ISO 9001:2015
Products	Changed to 'Products and services'
Exclusions	No longer used
Management representative	No longer used
Documentation, Quality Manual, documented procedures, records	Now referred to as 'Documented information'
Work environment	Changed to 'Environment for the operation of processes'
Monitoring and measuring equipment	Changed to 'Monitoring and measuring resources'
Purchased product	Changed to 'Externally provided products and services'
Supplier	Changed to 'External provider'

Comparing last versions and Why it is Important?

- **Products and services:** Previously ISO 9001:2008 used the term 'product' to include all output categories. This has always been a bone of contention with many non-manufacturing companies and so ISO 9001:2015 has now changed this term to 'products and services' to include all output categories (hardware, services, software and processed materials).
- **Understanding the needs and expectations of interested parties:** Organisations need to demonstrate their ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

Comparing last versions and Why it is Important?

- **Risk-based thinking:** Previously ISO 9001:2008 had a separate clause for 'preventative action'. ISO 9001:2015 now requires an organisation to determine risk as a basis for planning and implementing Quality Management System processes and overall improvements.
- **Applicability:** Although ISO 9001:2015 no longer contains '**exclusions**' regarding the applicability of its requirements to the organisation's Quality Management System, organisations can still review the applicability of the standard's requirements with regard to the size/complexity of their organisation, the management model it adopts, the range of the organisation's activities and the nature of the risks and opportunities it encounters.

Comparing last versions and Why it is Important?

- **Documented information:** In alignment with other management system standards, the term 'documented information' is now used in ISO 9001:2015 for *all* document requirements (e.g. 'document', 'documented procedures', 'Quality Manual', 'Quality Plan' or 'records').
- **Organisational knowledge:** To ensure the operation of its processes and so that it can achieve conformity of products and services, ISO 9001:2015 emphasises the need for organisations to determine, manage and maintain their knowledge base.

Comparing last versions and Why it is Important?

- **Control of externally provided processes, products and services:** It is now recommended that organisations apply risk-based thinking in order to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.

Annex SL

- It's a rule book for standard writers setting out what they must and must not do in the development of any international standard.
- As well as ISO 9001 for QMSs, ISO also publishes (see Chapter 6) a number of other Management Systems Standards (MSS) (e.g. Environmental, Occupational Health & Safety, Risk, Business Continuity, Information Security, Asset Management Systems) and, of course, there are many other standards that are actually based on ISO 9001 (such as ISO/IEC 27001 for information security management systems, etc.). Nevertheless, the structure and format of each of these standards is currently very different and so it is not surprising, therefore, that these variations continue to cause problems for organisations who have to become certified against multiple schemes.

Annex SL

- With the introduction of Annex SL, all of the major clause numbers and titles of all ISO management system standards will now be **identical**, such as the **introduction**, **scope** and **normative references** (whose content will be specific to each discipline), terms and definitions (22 terms and definitions have been listed which must be addressed; they cannot be deleted or changed – however, each standard can add their own additional terms and definitions if required and also add to or modify the notes written against these stated terms and definitions) and operation. ISO has, however, said that as an option, each standard may have its own bibliography!

What is the new structure of Annex SL?

The structure of Annex SL now concerns 10 main clauses instead of the previous 8 used by ISO 9001:2008 and other similar management standards, as shown below:

Clause 1: Scope: The scope sets out the **intended results** of the management standard (see Clause 4).

Clause 2: Normative references: Provides details of the **reference standards** or publications relevant to the management standard.

Clause 3: Terms & definitions: Details terms and definitions applicable to the management standard in addition to any formal related terms and definitions.

What is the new structure of Annex SL?

Clause 4: Context of the organisation: Clause 4 is the basic foundation of any management system. It will determine:

- why the organisation is here;
- how the organisation is structured;
- which internal and external issues can impact on its intended outcomes;
- who are their potential clients and what are their requirements. This in turn will need to be documented in the scope of the particular standard,
- which will then set the boundaries of the management system – i.e. ‘what’s in’ and ‘what’s out’.

What is the new structure of Annex SL?

Clause 5: Leadership: The new high-level structure places particular emphasis on leadership, not just management as set out in previous standards. This means that Top Management will now:

- have greater accountability and involvement in the organisation's management system;
- need to integrate the requirements of the management system into the organisation's Core Business Process;
- need to ensure the management system achieves its intended outcomes;
- need to allocate the necessary resources. Top Management is also responsible for communicating the importance of the management system and heightening employee awareness and involvement.

What is the new structure of Annex SL?

Clause 6: Planning

- Risk-based thinking is probably the most important requirement for the new version of ISO 9001, and once an organisation has highlighted the risks and opportunities in their product or service, they will then need to decide how and when these risks will have to be addressed and, most importantly, by whom.
- This new risk approach is a major change to management systems and **replaces preventative action** which will, in turn, **reduce the need for corrective actions** later on.

What is the new structure of Annex SL?

Clause 7: Support: Having thought about their overall organisational aims and policies, commitment and planning, organisations will now have to consider what resources are required to meet their goals and objectives.

Clause 8: Operation: Clause 8 contains the **lion's share** of management system requirements, addressing:

- in-house and outsourced processes;
- overall process management;
- sufficient criteria to control these processes; and
- ways to manage planned and unintended change.

What is the new structure of Annex SL?

Clause 9: Performance evaluation: Clause 9 determines:

- what, how and when things are to be monitored, measured, analysed and evaluated;
- how, when and by whom internal audits are conducted so as to ensure that the management system conforms to the requirements of the organisation as well as the selected management standard;
- how the organisation's management system is successfully implemented and maintained;
- how management reviews are organised and conducted to determine whether they are, and can remain, suitable, adequate and effective.

What is the new structure of Annex SL?

Clause 10: Improvement: It is a well-known fact that in an ever-changing business world, not everything will always go according to plan and so Clause 10 looks at ways to address nonconformities and corrective action, as well as suggesting strategies for improvement on a continual basis.

What is Quality?

- **'Quality'** (although an everyday word) is often **misused, misquoted** and **misunderstood**.
- When most people talk about the quality of an object, or service, they are normally talking about its **excellence, perfection** or its **value**.
- In reality, of course, they should be talking about how much it meets its **designed purpose** and **satisfies the original requirements**. Take for example a £50,000 Mercedes and a £19,000 Ford. It would be very unfair to suggest that the Mercedes is a better-quality car simply because it costs more! Being realistic, both cars meet their **predetermined quality requirements**.

What is Quality?

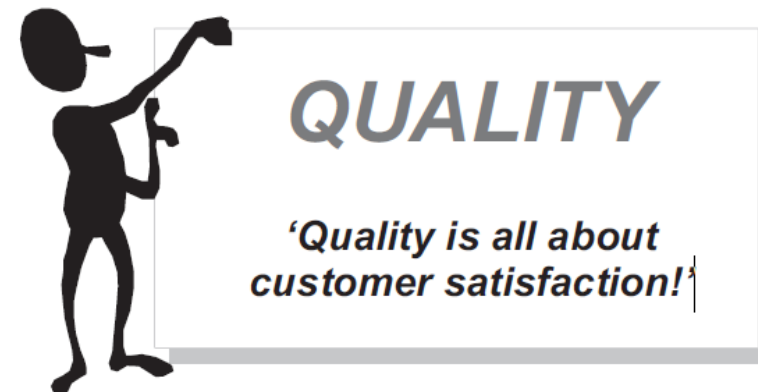
- **ISO Definition** : *The totality of features and characteristics of products and services that bear on its ability to satisfy stated or implied needs.*
- In other words, quality is based on **consumer satisfaction**.
- Consumers, however, are not just interested in the level of quality **intended** by the **designer**, **manufacturer** or **supplier** – they are **far more** interested in the delivery of a product or service which is **consistently of the same quality**.

In summary, 'quality' is :

- A standard which can be accepted by both the **supplier** *and* the **customer**;
- Giving **complete satisfaction** to the customer;
- **Complying consistently** with an **agreed level** of specification;
- Providing products and services at an **acceptable cost**;
- Providing products and services that have **auditable proof** that they are '**fit for the purpose**'
- *The totality of features or characteristics of a product or service that bear on its ability to satisfy a given need.*

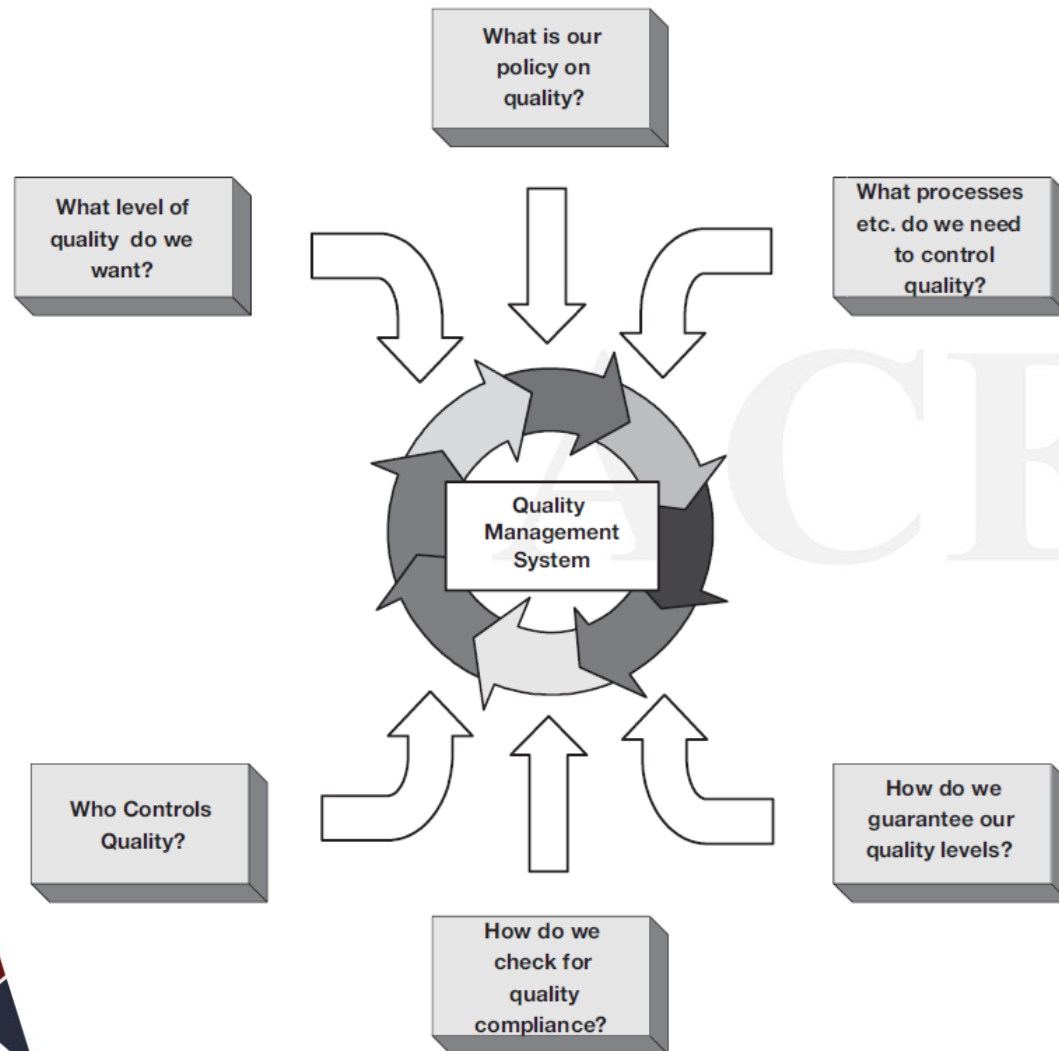
Quality is not about:

- Complying with a specification (as it is possible that the specification may be wrong!);
- Being the best (since achieving this ideal may be **very costly** and could **exceed the price** that the customer is **prepared to pay**);
- Producing products and services that are '**fit for the purpose**' at the point of **delivery** – as that 'purpose' may be completely different to the customers' actual needs!



Why QMS is required?

- Products and services that are of a consistent quality mean that **repeat purchases are more likely**.
- Organizations have had to set up **proper Quality Management Systems** in order to control and monitor **all stages** of the **product** or **service process**, and they have had to **provide proof** to the **potential customer** that these will have the **guaranteed** and in some cases **certified quality required** by the customer.
- In other words, the manufacturer or supplier has had to **work within a Quality Management System** to produce their products or deliver their service.



Some of the questions answered by a Quality Management System

Why QMS is required?

- The **growing demand** for an **assurance of quality before a contract** is awarded has reinforced the *already accepted adage* that *quality products and services* play an important role in *securing new markets* as well as *retaining those markets* that already exist
- The drive towards more *quality-led products and services* now means that today's major purchasers are not just expecting them to be of sufficient quality, but are also **demanding proof** that an organisation is capable of *continually producing* quality products or providing quality services.
- The **provision** of this proof is normally in the form of an **independent third party certification**.

QUALITY CONTROL AND QUALITY ASSURANCE

- **'Quality'** Verifies the quality of the output
- **'Control'** The ability to distinguish what is 'good' (i.e. meets requirements) and what is 'bad' (doesn't meet requirements)
- **'Quality Control'** The operational techniques and activities that are used to **fulfil** requirements for **quality**

ISO

Quality Control

Part of quality management focused on fulfilling quality requirements.

QC is primarily aimed at the **prevention** of errors. Yet, despite all efforts, it remains **inevitable** that errors will be made. Therefore, the control system should have checks such as the following to detect these:

- **what error was made?**
- **where was it made?**
- **when was it made?**
- **who made it?**
- **why was it made?**

Only when **all** these questions are answered can proper action be taken to correct the error and prevent the same mistake being repeated.

QC is exercised at all levels and as all personnel are responsible for the particular task they are doing, they are *all* Quality Controllers to some degree

Quality Assurance

*The assembly of **all planned and systematic actions** necessary to provide **adequate confidence** that a product, process, or service **will satisfy** given quality requirements.*

- **Quality** Fitness for intended use
- **Assurance** A declaration given to **inspire confidence** in an organisation's capability
- **Quality Assurance** A declaration given to inspire confidence that a particular organisation is capable of **consistently** satisfying needs as well as being a **managerial** process designed to increase confidence.

Quality Assurance

QA is concerned with:

- An **agreed** level of quality;
- A **commitment** within an organisation to the fundamental principle of **consistently supplying the right quality product**;
- A commitment **from a customer** to the fundamental principle of only accepting the right quality product;
- A commitment within all levels of contractor and/or customer to the basic principles of QA and QC.

WHO IS RESPONSIBLE FOR MANAGING QUALITY IN AN ORGANISATION?

In the current 2015 edition of ISO 9001, the **role of 'Management Representative'** (i.e. Quality Manager) has been **eliminated** as this responsibility has now become:

*“A management approach centred on quality based on the **participation of all its members** and aiming at **long term success** through **customer satisfaction** and **benefits to all members** of the organisation and society.”*

Which, in other words, means that **everyone in the organisation** is now **collectively responsible** for the **quality of the organisation**, its **products** and its **services**!

WHAT IS THE DIFFERENCE BETWEEN A PRODUCT AND A SERVICE?

- **Product** – is an **output** that is the **result of a process** that **does not include** activities that are performed at the interface between the supplier (provider) and the customer. **(ISO)**
- **Service** – is the **result of a process** that **includes at least one activity** that is carried out at the interface between the supplier (provider) and the customer. **(ISO)**
- There are **three** generic product and service categories: **hardware, processed materials and software**. Many products and services combine several of these categories.
- For example, a car consists of hardware (e.g. tires), processed materials (e.g. lubricants) and software (e.g. engine control algorithms).

QMS Definition

A set of **interrelated** or **interacting** elements to establish the **overall intentions** and **direction** of an organisation **related to quality** as **formally** expressed by Top Management and to achieve those objectives.

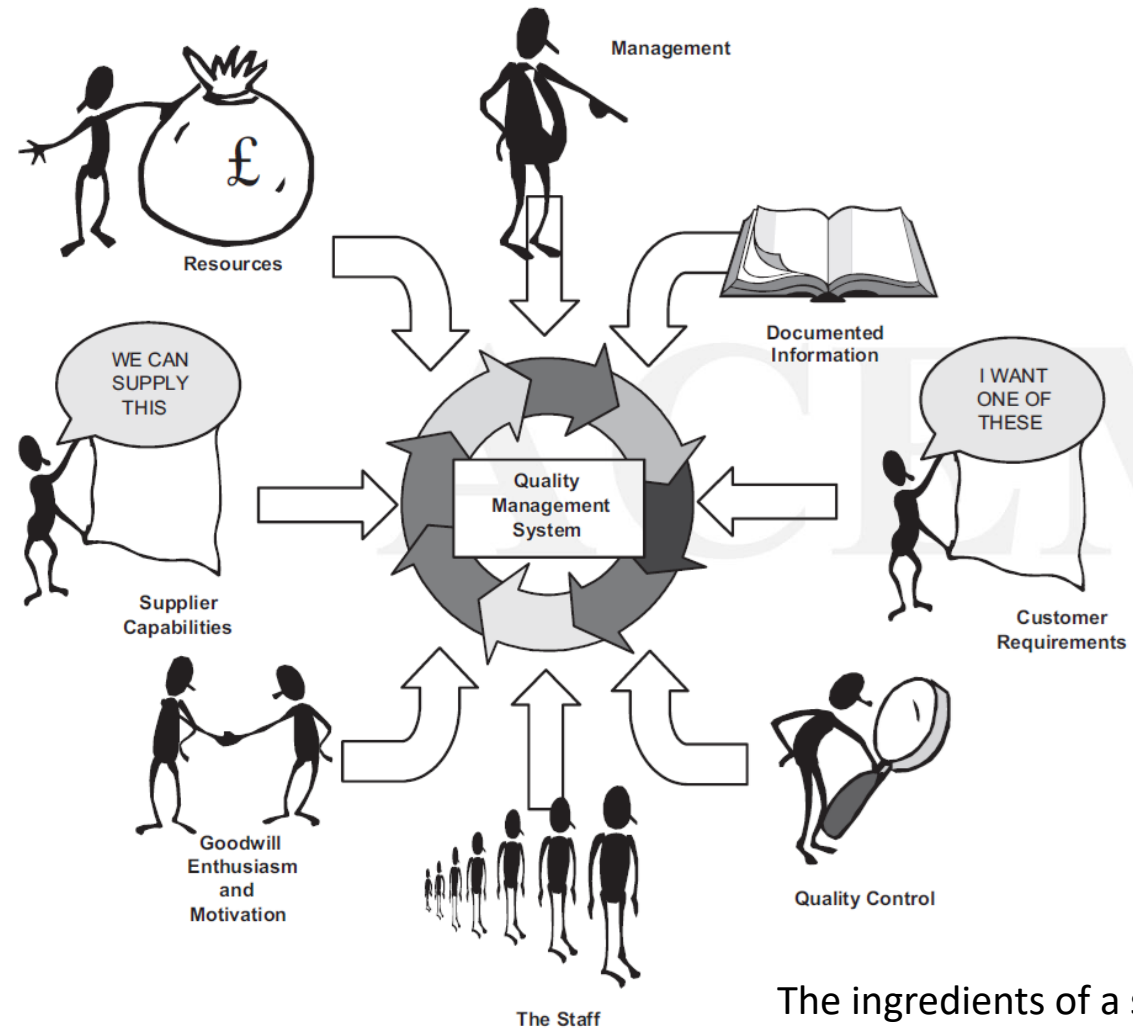
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ISO 9000

Or to put it another way, it is the **structure, policies, procedures, processes** and **resources** needed to implement a **quality managed structure of organizational responsibilities, activities, resources** and **events** that together provide **processes** focused on **achieving Quality Policy** and **quality objectives** to meet **customer requirements**.

QMS Role

Thus a company controls its business through the application of a ***business management system***, *not* – as the previous ISO 9001:2008 standard suggested – through a Quality Management System. So one mustn't get **too hung up** on the word '**quality**'!



The ingredients of a successful Quality Management System

QMS Documents

- Together, **these documents** comprise the organisation's Quality Management System and describe their capability for supplying products and services that will comply with laid-down quality and other regulatory standards.
- **Previously** this was contained in the '**Quality Manual**', which was a document setting out the **quality policies, systems and practices of an organisation's Quality Management System**.
- With the introduction of ISO 9001:2015, the International Standards Organization (ISO) Committee responsible for updating the standard **left out the requirement** for an organisation to **possess a formal Quality Manual** – preferring to call everything associated with an organisation's documents and records '**documented information**'.

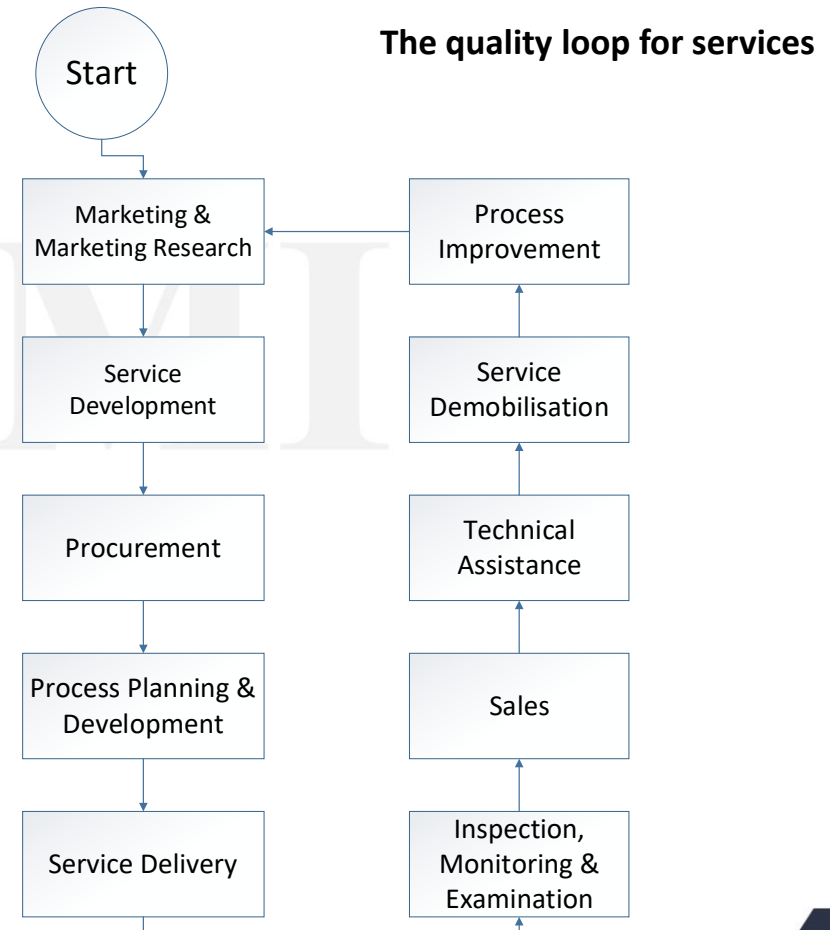
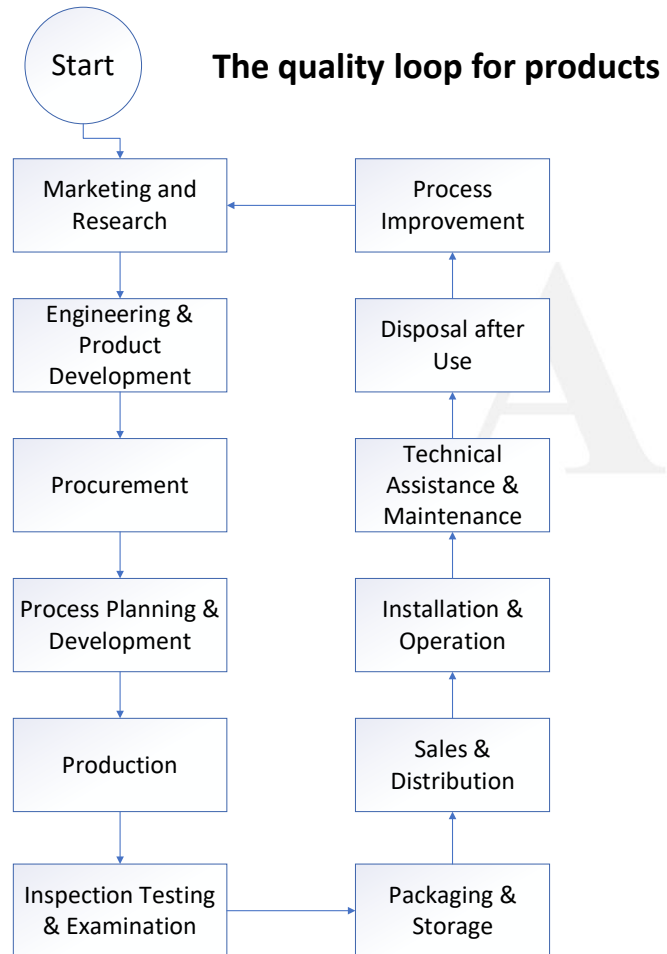
QMS Documents

In order to be successful an organisation **must be able to prove** that it is **capable** of producing products and services that **meet the customer's complete satisfaction** and which not only conform to the customer's specific requirements but are always of the desired quality.

An organisation's QMS is, therefore, the **organisational structure of responsibilities, procedures, processes** and resources for **carrying out Quality Management**. As such, it must be **planned** and **developed** so that it is **capable** of maintaining a **consistent level** of QC.

The 'quality loops' shown in next page should **always be followed** by an organisation to ensure that **all aspects** of the production and supply cycles have been considered in the QMS.

QMS Loops



QMS Documents

- However, to be **effective**, the QMS must be **structured to the organisation's own particular type of business** and should be **flexible** enough to consider all functions such as customer liaison, design, purchasing, subcontracting, manufacturing, training, installation, updating of QC techniques and the **accumulation of quality records**.

WHAT ARE THE REQUIREMENTS OF A QUALITY MANAGEMENT SYSTEM?

To be successful, an organisation (whether large or small) must:

- be able to offer products and services that satisfy a customer's expectations;
- agree with the relevant standards and specifications of a contract;
- be available at competitive prices;
- be able to supply products and services at a cost that will still bring a profit to that organisation.

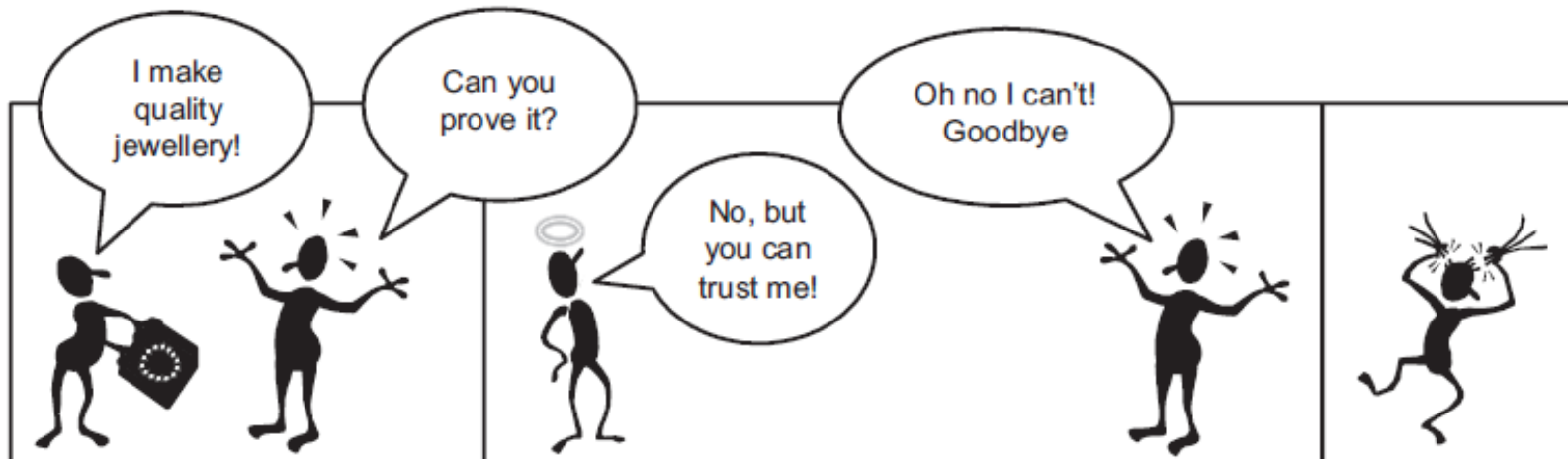


Organisations must, above all, **provide quality products and services** that will **promote** further procurement and recommendations.

Why ISO Certificate?

- So, how can your organisation become a Quality organisation?

No proof of quality = no business



Why ISO Certificate?

- So, how can your organisation become a Quality organisation?

The benefits of proof



The **easiest** and **most recognised/ generally accepted** way is to work **in conformance with** the **requirements of ISO 9001:2015**. This standard provides guidelines for organisations wishing to establish **their own QMS** and thereby control the quality of their organisation – from within their organisation.

QMS requirements generally cover the following topics

- organisational structure;
- measurement of QA;
- contract specification;
- design control;
- purchasing and procurement;
- production control;
- product and service testing;
- handling, storage, packaging and delivery;
- after-sales service;
- risk analysis.

The main benefits of Quality Management

- An **increased capability** to **provide products** and **services** that **consistently** conform to **agreed specifications**;
- A **reduction in administration** and **production costs** because of **less wastage** and **fewer rejects**;
- A **greater involvement** and **motivation** within an organisation's workforce;
- **Improved customer relationships** through fewer complaints, thus increasing sales potential.

Personnel approach to QMS:

For an organisation to derive any real benefit from a QMS, everyone in the organisation must

- Fully appreciate that QA is absolutely essential to its future;
- Know how they can assist in achieving quality;
- Be stimulated and encouraged to do so.



Elements of QMS : Quality Manual

- Since the first edition of ISO 9001, it has been an accepted fact that a Quality Manual is '**a document specifying the Quality Management System of an organisation**'.
- A Quality Manual is recognised as an **official document** produced by an organisation that details **how its Quality Management System operates**.
- Quality Manual will include the company's **Quality Policy** and **goals**, as well as a **detailed description of its QC system** including **Staff** roles and **relationships, procedures, systems** and any other **resources** that relate to producing high-quality goods or services.
- With the introduction of ISO 9001:2015 the ISO Committee responsible for updating the standard **removed** the requirement for an organisation to possess a formal Quality Manual

Elements of QMS : Quality Manual

- Whatever the final ruling regarding the title of this particular document, it will become the **formal record of its QMS** and it will be:
 - a rule book by which an organisation functions;
 - a source of information from which customers may derive confidence;
 - a means of defining the responsibilities and interrelated activities of every member of the organisation;
 - a medium for defining the level of quality that an organisation wishes to consistently deliver;
 - a vehicle for auditing, reviewing and evaluating the organisation's QMS.

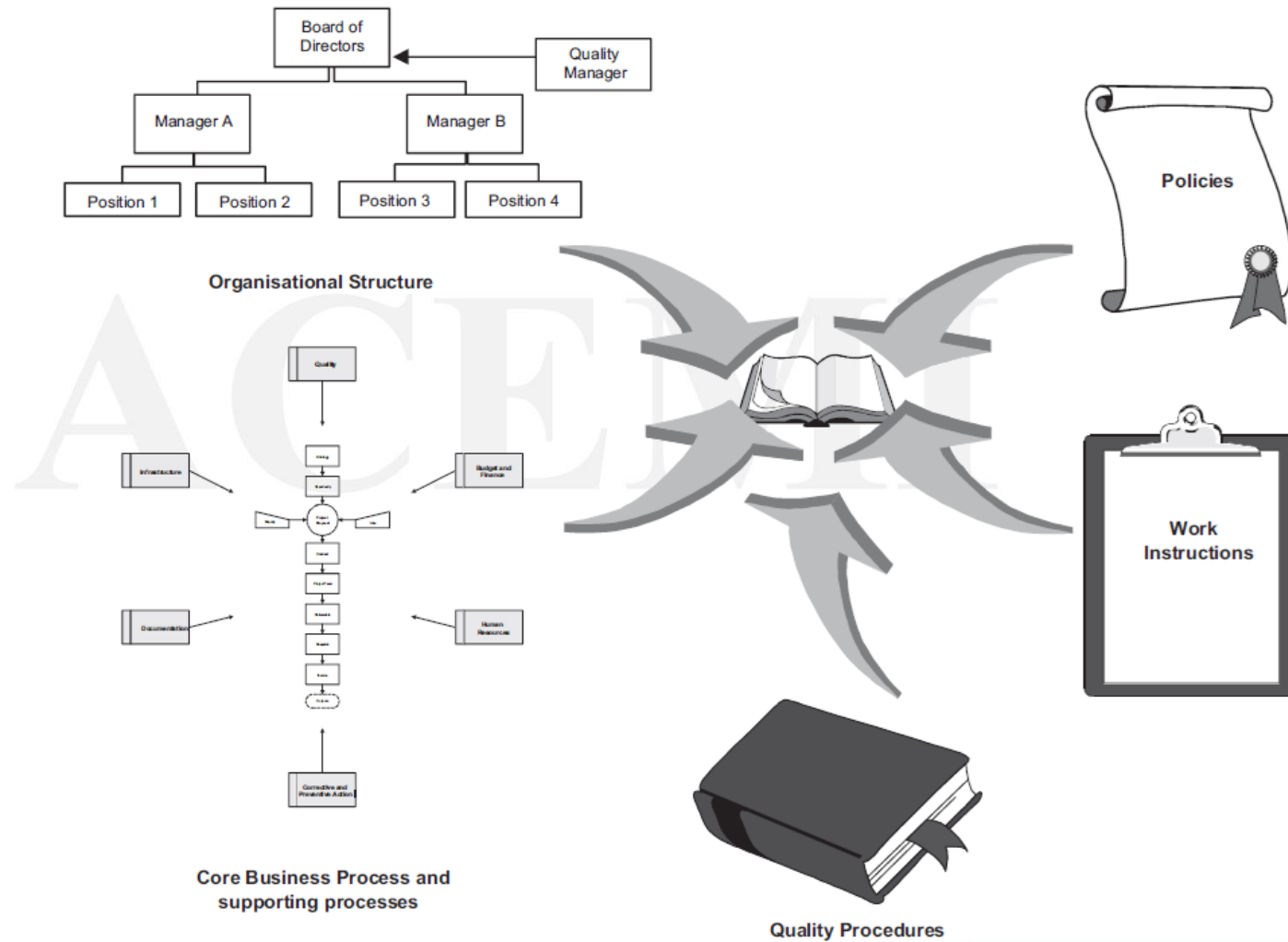
Elements of QMS : Quality Manual

- As the quality processes and procedures, etc. of an organisation are all interrelated, there must be some sort of **centralised library** for these documents (be they hardcopy or digitised copies) and surely the **most logical place** for these is in a file called the '**Quality Manual**' – a document that **has existed** and has been used by **auditors** and Quality Managers for more than 50 years!
- At the time of writing this book, the 'jury' still appears **to be out on** this 'ruling' and many organisations (particularly those already ISO 9001:2008 certified) **intend to continue using their existing, albeit slightly modified, Quality Manual** so as to include the changes made by ISO 9001:2015.

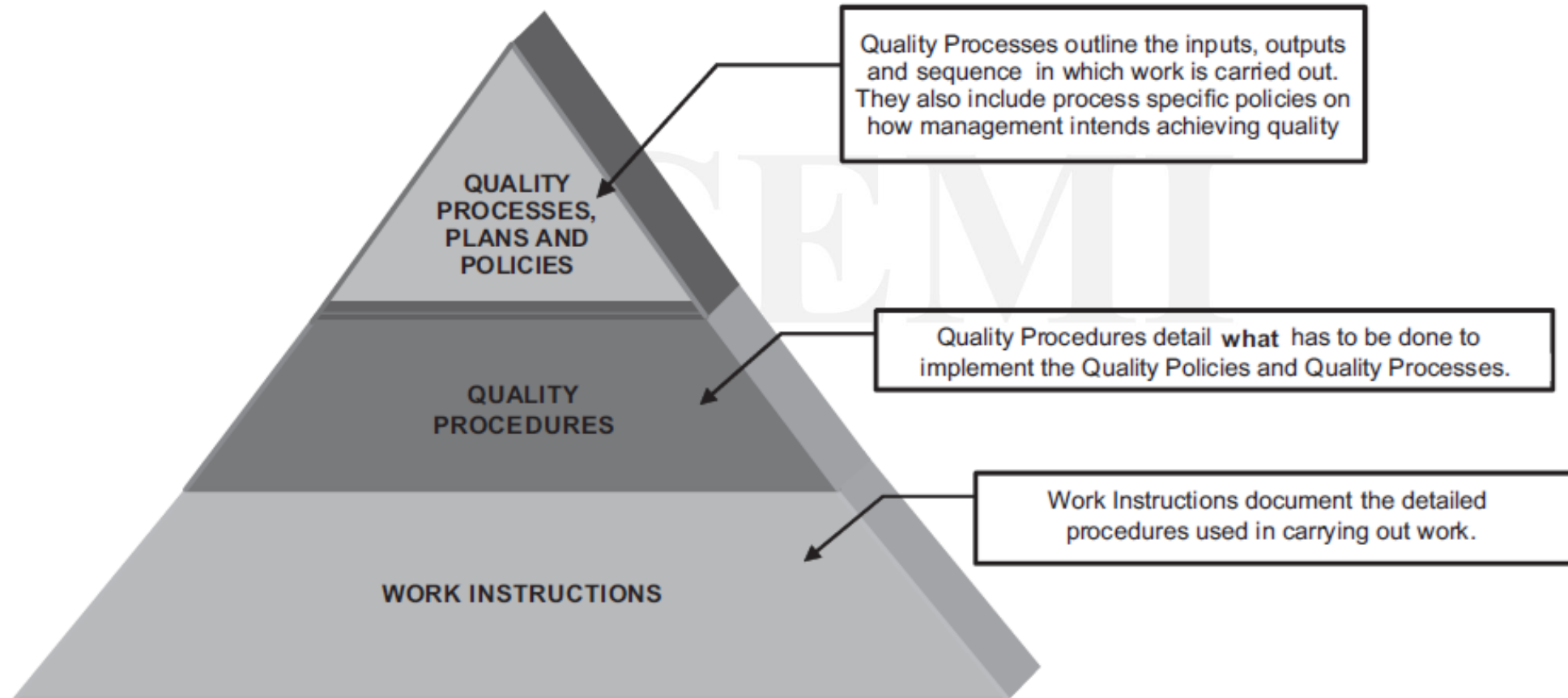
What goes into quality manual?

- The answer to ‘what goes into a Quality Manual’ is virtually **anything** and **everything**, and depends on what you need in order to run your business efficiently.
- Whatever the size of your organisation and whether you produce, install or merely use a product or service, the overall purpose of the Quality Manual is to act as your **organisation’s overarching policy ‘bible’**, which (if required) will identify subsets of **Quality Processes, Quality Plans, Quality Procedures** and **Work Instructions** and **provide templates** of the various **forms** and **documents** used by your organisation – such as production control forms, inspection sheets and documents used to purchase components from your sub contractors.

The basic contents of a Quality Manual



What does each part of the Quality Manual do?



WHAT IS A QUALITY POLICY?

- A Quality Policy is a statement of an organisation's **overall quality intentions** and the **direction** of an organisation regarding **quality** which is **formally expressed** by **Top Management**.
- It **outlines** how management **intends to achieve quality** and **dictates** how every other aspect of an organisation's QMS is **set up** and **run**.
- There are three types of policy statement that an organisation needs:
 - ❑ **Mission Statement:** A very brief, high-level statement of intent from senior management;

WHAT IS A QUALITY POLICY?

- ❑ **Corporate Policy Statement:** An expansion upon the Mission Statement;
- ❑ **Process-specific policies:** Clear statement of intent for each process performed by a business.

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Mission statement

Whilst ISO 9001:2015 does not directly call for a mission statement, it is ideal as a means of starting a QMS as it is aimed at **polarising** the mind and pointing everyone within a business in one particular direction. This high-level policy statement should be focused on customer satisfaction and:

- be appropriate for the needs of the organisation and its customers;
- involve everybody within the organisation;
- outline the organisation's goals and objectives;
- be communicated and implemented throughout the organisation;
- be understood by everyone.

Mission statement

Mission statements should ideally be **short** and capable of being **instantly memorised**, e.g.:

We, the LUR company, aim to deliver effective, evidence-based management products and systems in accordance with the recommendations of ISO 9001:2015 and other industry equivalent standards.

Mission statement

Mission statements have certain things in common, in that they:

- define a **goal for the business**;
- state **corporate values**;
- start to **define measurable objectives**;
- **imply a need** for employee competence;
- address **risk management**;
- address **customer satisfaction**;
- provide a **lead** towards continual improvement.

Corporate Policy Statement

- if an organisation is **serious** about **setting up a QMS**, then **Top Management must commit itself** by **stating** their **policies** on **quality**. Without a **firm commitment** from senior management, an organisation's QMS will **fail**. This **Corporate Policy Statement (CPS)** is usually achieved by management putting together a document that **outlines** their **intentions**, based upon their **mission statement**.

Corporate Policy Statement

This high-level policy statement should be focused on customer satisfaction and:

- be **appropriate** for the **needs of the organisation** and its **customers**;
- involve **everybody** within the organisation;
- outline the organisation's **goals** and **objectives**;
- be **communicated** and **implemented** throughout the organisation;
- be **understood** by **everyone**.

Corporate Policy Statement

- ISO 9001:2015 **unintentionally** gives us some guidance in putting together a policy statement, in so much as the standard is based upon **seven Quality Management Principles**.
- By establishing your policy against these principles you should end up with a robust statement.

Corporate Policy Statement

The policy of this company is to achieve and maintain a high standard of management in all aspects of our operation and to continually satisfy the expectations of our customers.

We will conduct our business through the following principles:

- **Customer focus:** We will deliver products and services that comply with our predetermined requirements which recognise the needs and expectations of our customers.
- **Leadership:** We will provide direction for the business by establishing clear objectives that serve to fulfil business goals.
- **Engagement of people:** We will develop our business through the involvement of our Staff, by utilising their knowledge and experience.
- **Process approach:** We will run our business through a structured process-based management system and will ensure that all our Staff work to the requirements of this system.
- **Improvement:** We will commit to enhancing our management system through the proactive identification and implementation of improvement opportunities.
- **Evidence-based decision making:** We will make informed business decisions using the analysis of data obtained from suitable metrics.
- **Relationship management:** We will develop relationships with our suppliers and work with them to improve sub-contractor performance.

Signed _____
Managing Director

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

1. Customer Focus
2. Leadership
3. Engagement of People
4. Process Approach
5. Improvement
6. Evidence-based Decision Making
7. Relationship management

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

- As stated in the standard, ISO 9001:2015 is the internationally recognised standard for ***all Quality Management Systems***. As such, it provides the **benchmark** against which a **company's management system** is measured and, if found to be adequate, **certified as compliant**. Consequently, for this standard to be seen as the leading example of management system methodology, it has had to reflect currently accepted best practice.
- With this in mind, the standard was developed to be totally **business focused**, and aimed at **improving an organisation's management system** through the **application of seven proven principles**, as stated below:

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

1- Customer focus

Seeking to satisfy the demands and expectations of the customer. Organisations depend on their customers and should, therefore:

- understand current and future customer needs;
- meet customer requirements (and their budget!)
- **strive to exceed customer expectations.**



*The primary focus of Quality Management is to meet customer requirements and to **strive to exceed customer expectations.***

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

2- Leadership

- Leadership is a core skill in today's business world; without strong leadership, many good businesses fail – and so can management systems.
- Leaders create the environment in which people can become fully involved in achieving the organisation's objectives.
- Without the right support and direction for your organisation you can't achieve your full potential.



Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives of the organisation.

Annex SL

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

3- Engagement of people

- ***‘Employee engagement’*** should aim at ensuring that all employees are **committed** to their **organisation’s goals and values**.
- People at all levels are the essence of an organisation, and their full involvement enables their abilities to be used for the organisation’s benefit.

*It is essential for the organisation that all people are **competent, empowered and engaged** in **delivering value**.*

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

4- Process approach

- The logical sequencing of activities to efficiently achieve a desired result.
- A desired result is achieved more efficiently when related resources and activities are managed as a process.
- *Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.*

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

5-Improvement

- It is essential for an organisation to maintain current levels of performance, to react to changes in its internal and external conditions in order to create new opportunities.
- The improvement of any organisation's Quality Management System and processes, etc. should become a permanent objective. Put simply, it means 'getting better all the time'.

*Successful organisations have an **ongoing focus on improvement**.*

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

6- Evidence-based decision making

- Decision making based on the analysis of data should always be based on facts and evidence.
- Effective decisions are based on the logical and intuitive analysis of data and information.
- Reliable data gathered via planned measures is the only way this can be achieved.

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

THE SEVEN PRINCIPLES OF QUALITY MANAGEMENT

7- Relationship management

- The mutual support of an organization and its suppliers adds value.
- Mutually beneficial relationships between an organisation and its suppliers enhance the ability of both organisations to create value.
- The supplier/customer relationship should always be viewed as an *interdependent* relationship.

For sustained success, organisations manage their relationships with interested parties, such as suppliers.

Process-specific policies

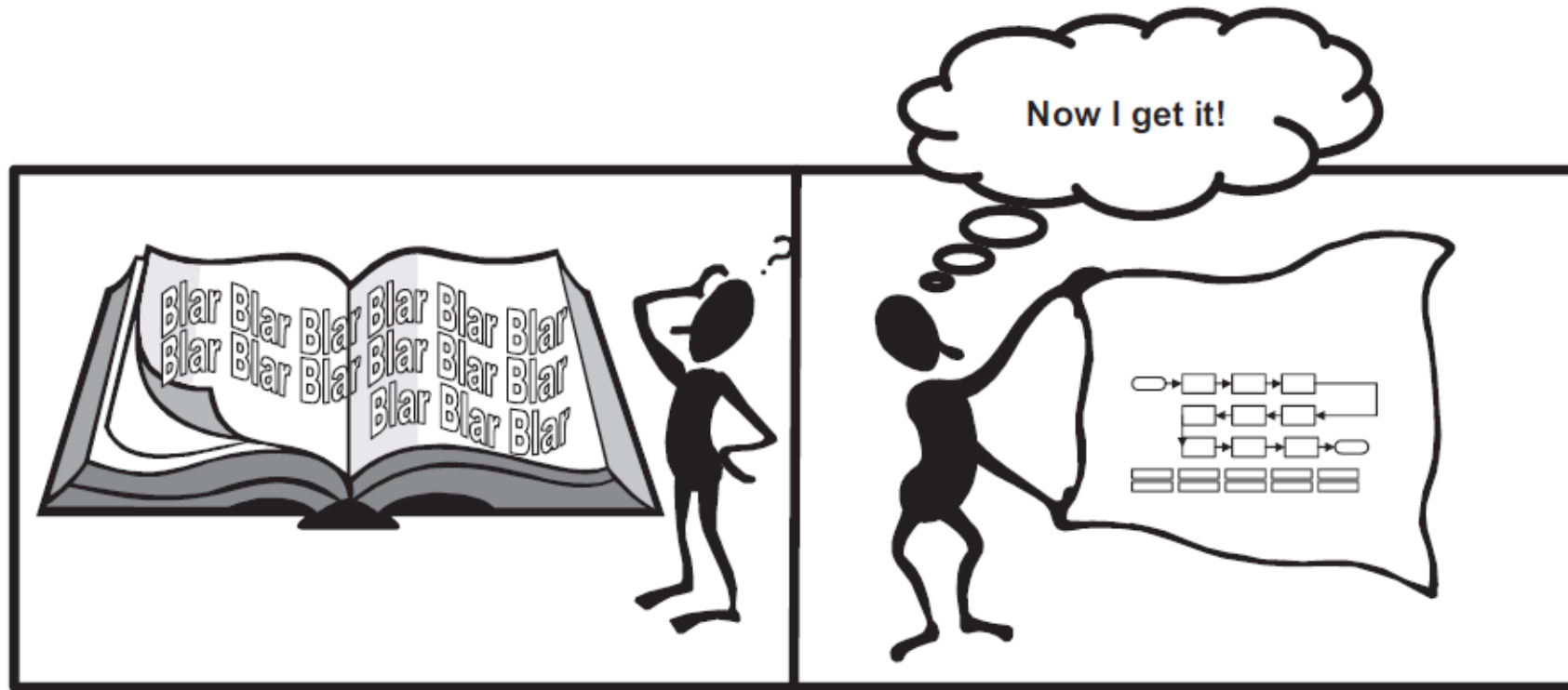
- To comply with the requirements of ISO 9001:2015, you will need to **determine, establish, implement, maintain** and **continually improve written processes** for your QMS and, in particular, the design and development of your products and services.
- To start getting things under control, you will need to **break down** these activities into a series of **inter-related processes** that describe **how** they **manage** your quality.
- Then once the **Core Business Process** and its **Supporting Processes** have been identified, it is then relatively straightforward to **define policies** for **each of the processes**.

Process-specific policies

- These processes will then probably need to be **supported** by a number of Quality Procedures(QPs).
- You are, of course, at liberty **to set down in words** as many procedures as you feel appropriate, remembering that ***procedures are generally*** used to **amplify** the detail shown on **process maps**.
- Just a word of warning; no one likes to read procedures on how to do things. **Process mapping** is the better option as it **visually** represents your business and so it is best to keep written **procedures** to a **minimum** and only **use** them **when** they are either **mandatory** (to your particular business) or will **add value** and **clarity** to a process map.

Process-specific policies

A picture paints a thousand words!



How to set Quality Objectives?

- As ISO 9001:2015 is quick to tell us, quality objectives are established to provide a **focus** to **direct** your **business** with the overall intention to **lay down** the **desired results** you **wish** to **achieve**, thereby enabling you to **apply resources** to achieve these goals.
- Quality objectives need to be **consistent** with the **high-level corporate Quality Policy** and in turn **relate** to the **process-specific policies**.
- There is one basic rule that needs to be applied when setting quality objectives, that being, think **‘S.M.A.R.T.’**

How to set Quality Objectives?

- **Specific:** A specific objective is one that can be observed and therefore verified against predetermined criteria.
- **Measurable:** The objective should be capable of being measured. For example in terms of percentages.
- **Attainable**
- **Realistic:** Realism in this context means whether the objective is realistically applicable to the people responsible for performing the task.
- **Timely :** No great surprise here. There is no point in setting an objective without specifying a time by which it should be achieved.

How to set Quality Objectives?

Objectives that are **S.M.A.R.T.** can be **monitored**.

How to go about setting measurable objectives?

- Simply ask yourself *what influences the way in which a process is performed*. These 'influences' are the known **variables** that will either make the process **succeed** or **fail**.

Measuring success criteria leads to meeting objectives

How to set Quality Objectives?

Policy Statement Extract	Objectives	Types of Indicator/KPI	Possible Targets
'We will achieve customer satisfaction'	Achieve a high level of service user satisfaction	Survey results rating	Achieve an overall rating of > 5.5 in 2019
		No. of customer complaints	Less than 2 complaints submitted in 2019
'by providing reliable systems'	Maintain a high level of system reliability	Time system is down during regular work hours	Systems downtime < 5% during working hours
'that meet customer requirements'	Ensure systems provided are fit for purpose	Survey results	Achieve "fit for purpose" rating of > 5 on survey
		User agreement after completion that the request meets the original specification	100% of completed requests signed off to indicate customer agreement
'We will respond as quickly as possible when contacted by a customer and we will work to meet agreed deadlines for all data requests'	Provide a responsive customer service	Compare actual request completions against the targets agreed with users	95% of work requests completed within deadline
'In the event of a serious incident, we will restore full system operation in the quickest possible time'	Maintain the ability to recover the systems in the event of a disaster	Time taken to recover from disaster (conduct annual or bi-annual test)	Recover system operation within 6 hours of a disaster

Linking Quality Policy, Objectives, KPIs and Targets

هدف شماره ۲: گسترش همکاری با اعضای زنجیره تامین و افزایش میزان رضایت ذی نفعان این گروه و مشتریان

Sample Quality Objective

اهداف خرد:

- افزایش میانگین نمره رضایت مشتریان
- تدوام همکاری با پیمانکاران قبلی
- سرعت و صحت رسیدگی به صورت وضعیت های پیمانکاری

شرح هدف	اهداف خرد	شاخص	میزان هدف	حد کنترلی	دوره پایش	مسئول پایش
گسترش همکاری با اعضای زنجیره تامین و افزایش میزان رضایت ذی نفعان این گروه و مشتریان	افزایش میانگین نمره رضایت مشتریان	میانگین امتیاز فرمهای ارزیابی رضایت	۸۰٪	۷۰٪	یک ساله	امور پروژه ها
	تدوام همکاری با پیمانکاران قبلی	نسبت تعداد قراردادهای منعقد شده با پیمانکاران قبلی به تعداد قرارداد منعقد شده با پیمانکاران جدید	۷۵٪	۵۰٪	یکساله	بازرگانی
	سرعت و صحت رسیدگی به صورت وضعیت های پیمانکاری	مدت زمان رسیدگی به صورت وضعیت های پیمانکاری	کمتر از دو هفته	حداکثر یک ماه	۶ ماهه	طرح و برنامه

برنامه های دستیابی:

ردیف	شرح برنامه عملیاتی	منابع مورد نیاز	مسئول پیگیری
۱	بررسی فرم های دریافتی و تحلیل علل رضایت / عدم رضایت کارفرما به همراه تهیه گزارش تحلیلی از آنها و ارائه راهکارهایی جهت بهبود مستمر میزان رضایت کارفرما	✓ منابع انسانی متخصص ✓ هماهنگی های مدیریتی	مدیر طرح و برنامه
۲	برگزاری جلسات مستمر با نمایندگان کارفرما جهت رفع علل نارضایتی های احتمالی	✓ منابع انسانی متخصص ✓ نرم افزارها و سخت افزارهای ارتباطی	مدیر طرح و برنامه مدیر امور پروژه ها
۳	ایجاد روابط مستحکم و برد متقابل با پیمانکاران و اعضای زنجیره تامین	✓ منابع انسانی متخصص ✓ هماهنگی های مدیریتی ✓ منابع مالی	مدیر بازرگانی
۴	بررسی صورت وضعیت های پیمانکاری در سریعترین زمان ممکن و کارسازی آن	✓ منابع انسانی متخصص ✓ نرم افزارهای مالی ✓ منابع مالی	مدیر طرح و برنامه

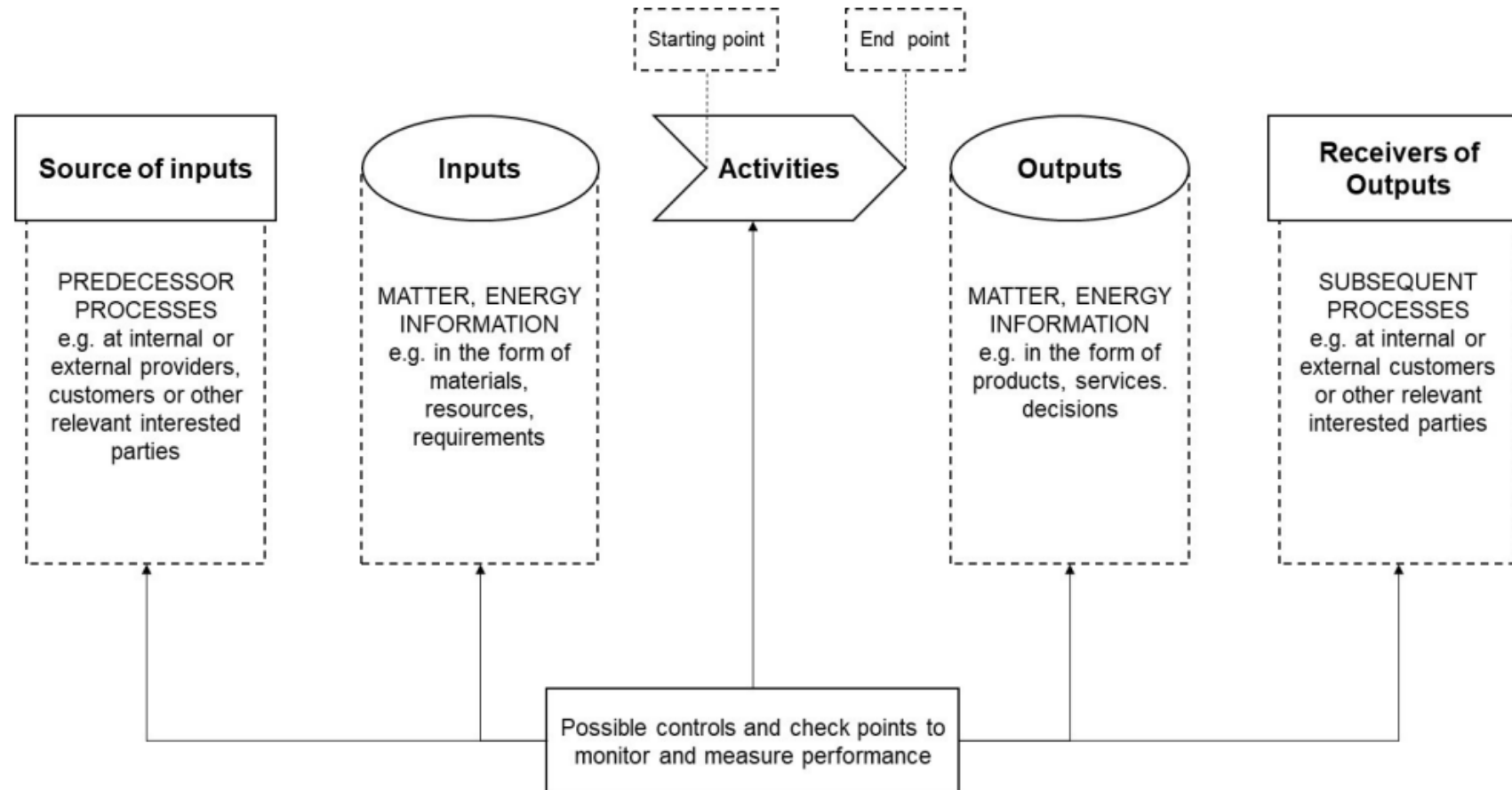
The Process Approach

- The ISO 9001:2015 standard **emphasizes a process approach**, which is fundamentally integrated with the **Plan-Do-Check-Act (PDCA) cycle**. This means that organizations should manage their activities **as interconnected processes**, utilizing the **PDCA cycle** to ensure processes are **planned, implemented, monitored, and continuously improved**.
- The process approach, **combined with risk-based thinking**, helps organizations achieve **consistent and predictable** results by managing processes **effectively** and identifying opportunities for **improvement**.

The Process Approach

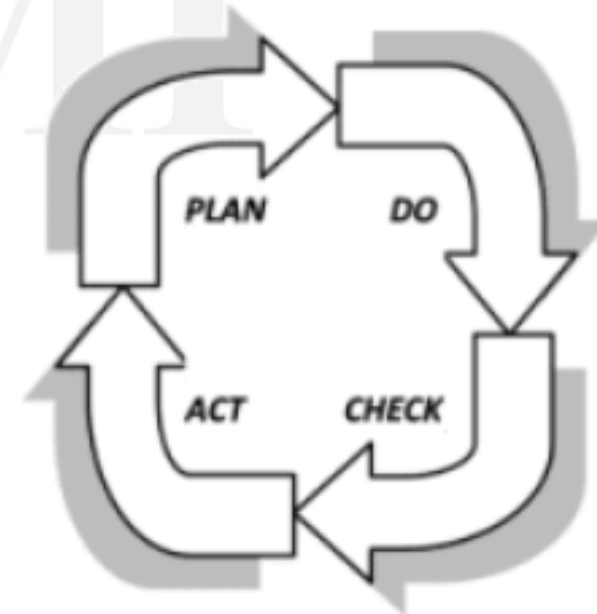
- ISO defines a Quality Process as ‘a **system** which uses **resources** to **transform inputs** into **outputs**’.
- Any activity that receives inputs and converts them to outputs can be considered as a process. Often, the **output from one process** will **directly** become the **input into the next process**.
- For organisations to function **effectively**, they will have to **identify** and **manage** numerous **interlinked processes**. This *systematic identification and management of the processes employed within an organisation* (and particularly the interactions between such processes) is referred to as the ‘**process approach**’.

Process Elements



PDCA Cycle

Plan-Do-Check-Act (also called “PDCA”) is a **cycle** that was originated by **Walter Shewhart** and made popular by **Edward Deming** – two of the **fathers of modern quality control**. This concept is a cycle for **implementing change** which, when **followed and repeated**, would lead to **repeated improvements** in the **process** it was applied to.

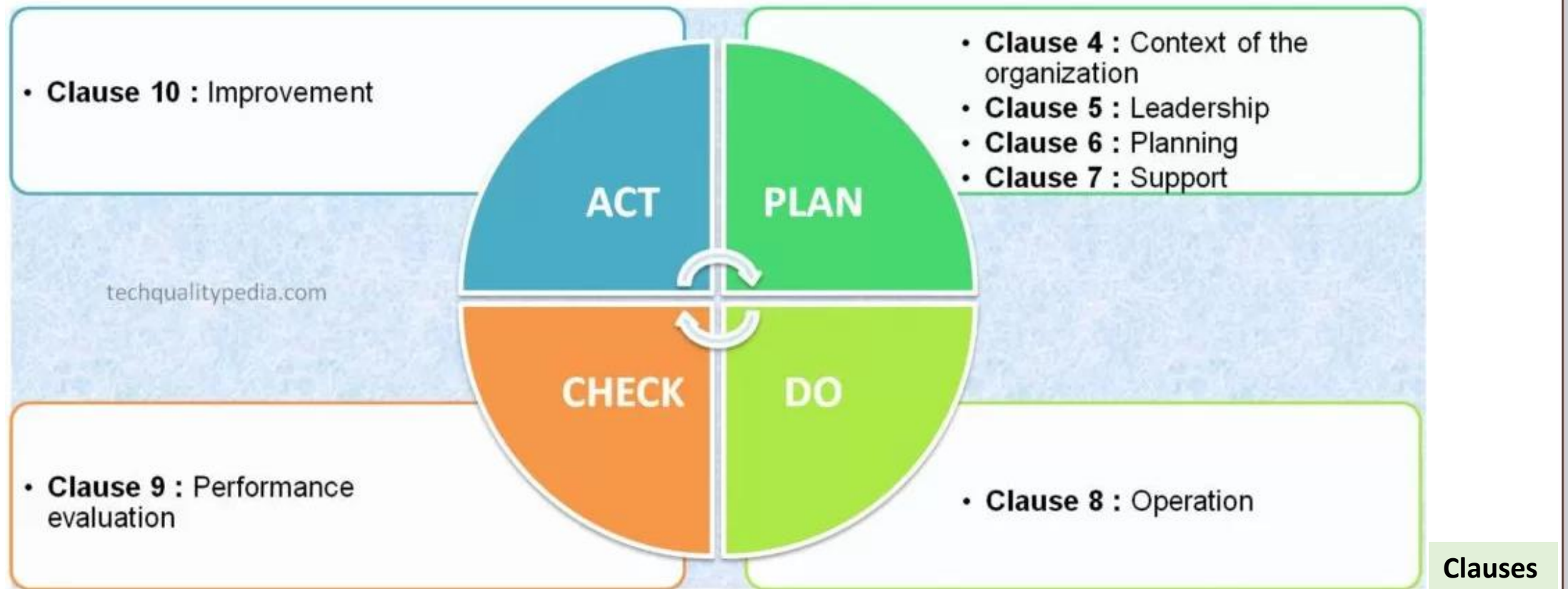


PDCA Cycle

PDCA Cycle: The PDCA cycle (Plan-Do-Check-Act) provides a structured framework for managing processes.

- **Plan:** Define objectives, establish processes, and set targets.
- **Do:** Implement the planned processes.
- **Check:** Monitor and measure processes against objectives and identify areas for improvement.
- **Act:** Take corrective actions and implement improvements to enhance process performance.

ISO 9001 clauses – arranged according to PDCA cycle



PDCA Cycle in ISO: Plan

Planning is one of the biggest parts of the QMS and starts with **understanding the context of the organization and the needs of parties interested in the QMS** (4.1 & 4.2), which is then used to **define the scope of the QMS** and the **QMS processes** (4.3 & 4.4). This is followed by the **commitment of leadership** in the company to drive the organization to a **customer focus** by **defining the organizational roles and responsibilities** and by **establishing a quality policy** to give the overall QMS a focus (5.1, 5.2 & 5.3). The next level of planning is to **identify and address risks and opportunities** of the QMS, including **setting and planning for quality objectives** and changes to **support continual improvement** (6.1, 6.2 & 6.3). The final level of planning is to identify and **implement the support structure** to allow you to carry out your plans.

PDCA Cycle in ISO: Plan

This includes **resources** (7.1), **identifying competence** (7.2), **awareness** (7.3), **communication** (7.4) and to **set the processes for creation and control of documented information** (7.5).

PDCA Cycle in ISO: Do

Planning is useless unless the plan is carried out. Controls need to be identified for the QMS operations, **product or service requirements** need to be **identified** (8.2), **designs developed** (8.3), controls placed on **externally provided processes, products and services** (8.4). The process of **producing** the **product** or service needs to be carried out with control of product and service **release** (8.5 & 8.6), **any non-conforming products** or services need to be **addressed** (8.7). In short, the activities of creating and providing products or services to the customers need to be done.

PDCA Cycle in ISO: Check

There are several requirements in the standard to check the processes of the Quality Management system to ensure they are functioning properly as they have been planned.

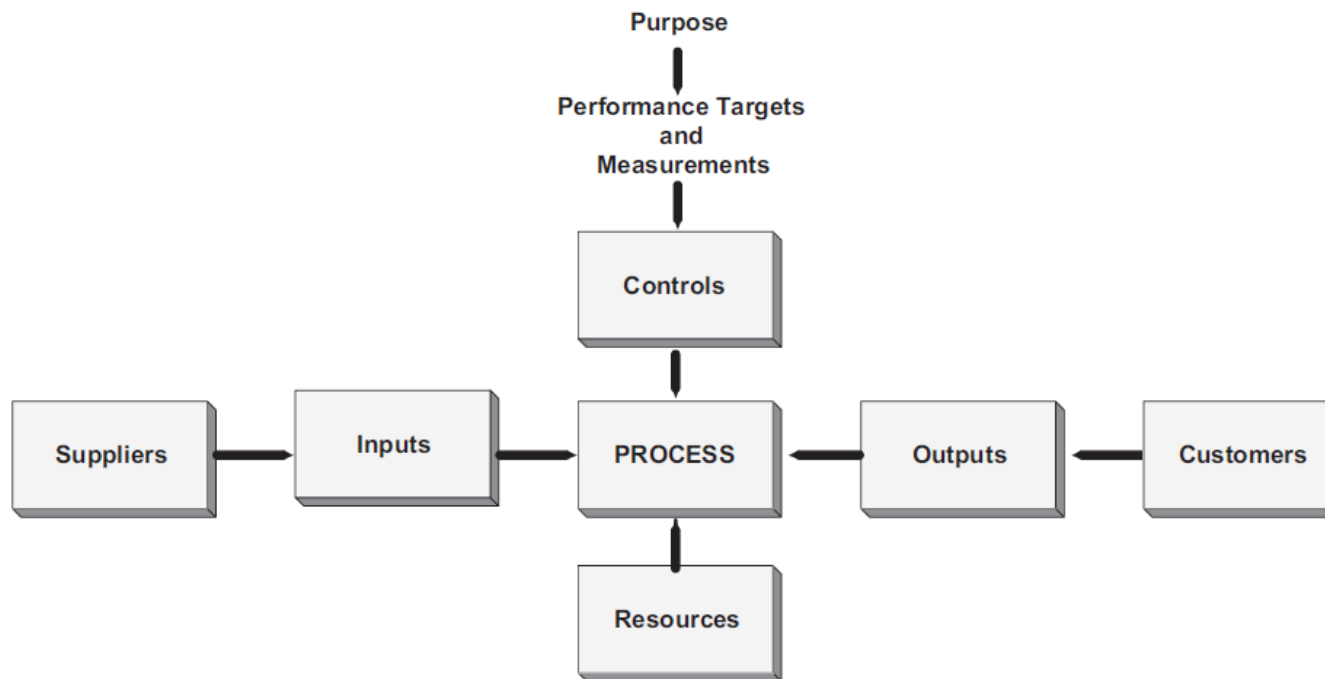
There is a need to monitor, measure, analyze and evaluate the products or services to ensure they meet requirements, the processes used are adequate and effective, and **customer satisfaction is being met** (9.1). **Internal Audit** (9.2) **set the processes** for creation is the key way to **assess the effectiveness** of the system. Further is the **Management Review process** (9.3), which reviews and assesses *all of the monitored data to make changes and plans to address the issues.*

PDCA Cycle in ISO: Act

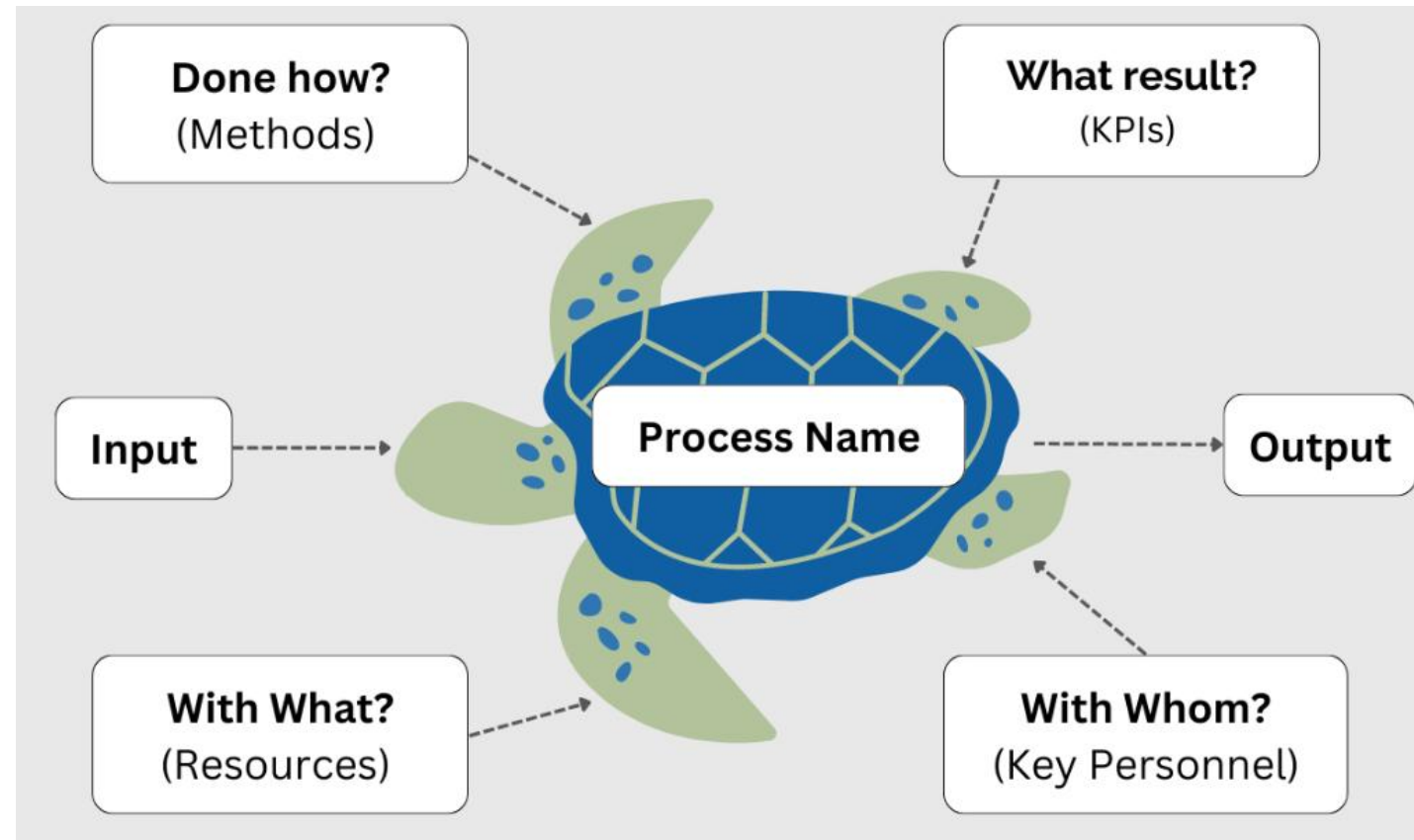
Action in this case involves *the actions needed to address any issues found in the check step*. **Improvement** (10.1 & 10.3) is the **overall heading** for these action steps (10.1) with the activities of **addressing nonconformity and Corrective Actions** (10.2) to **eliminate** the causes of **actual or potential nonconformities** as the first step in acting to improve the system.

ISO Processes

- In addition to inputs, outputs and Quality Controls, processes include **physical attributes** like **suppliers, customers** and the **resources** needed to perform the process.



ISO Processes – Turtle Diagram



ISO Process Elements

- **Purpose:** A short description of what the process is intended to achieve, i.e. what value it is adding to the business.
- **Performance targets and measures:** the predetermined performance levels you decide and the tangible metrics that are used to prove the process is performing.
- **Process owner:** Every process should have one designated owner who is accountable for its execution and its continued applicability.
- **Suppliers:** Consider this the source of inputs to a process. It could be another department or another process.

Items needed to define processes

- **Input:** Those items needed to produce the outputs. They should not be confused with the resources needed to perform the process. For example, a set of accounts could be the input needed for performing a financial analysis process.
- **Controls:** Those standards defined by yourself (or possibly legislation) that impact upon the way a process is performed.
- **Resources:** These can be:
 - **Personnel:** Define who is responsible for carrying out the process.
 - **Infrastructure:** Any equipment required to perform the process to an acceptable level.
 - **Support systems:** These could be computer software packages required to perform a specific activity.

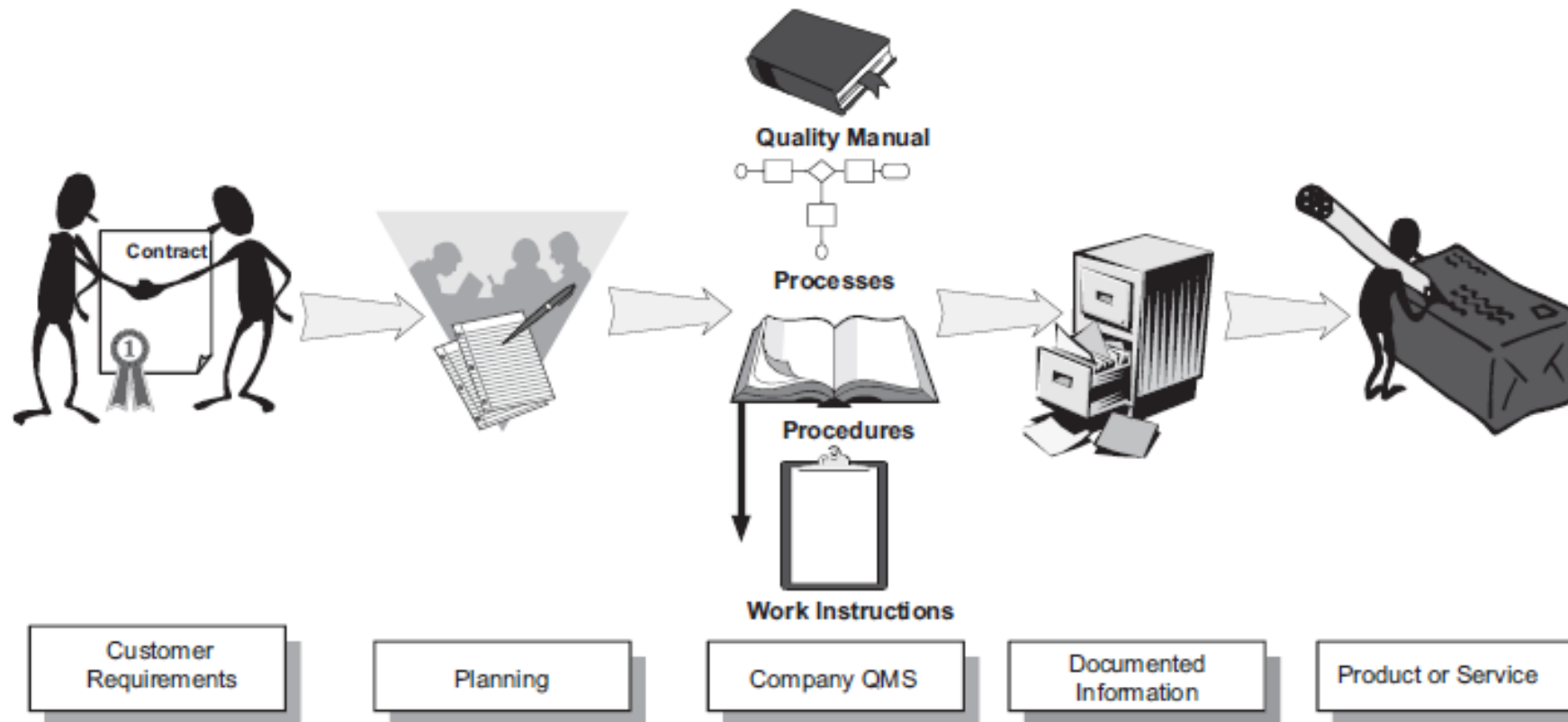
Items needed to define processes

- **Outputs:** The expected deliverable from a process. This 'may' form the input to another process, but in all instances it will add value to a business.
- **Customers:** Ultimately all processes deliver something (the output) to a customer, who could be the ultimate purchaser of a particular product or service or someone internal to your own business, such as a stores controller taking delivery of equipment from goods inward.
- All the above points should be considered before embarking upon drawing up a process.

Process Types in ISO

- In ISO 9001:2015, **Core Business**, **Primary Supporting** and **Secondary Supporting** processes are used in an **identical** way to *define how resources and activities are combined, controlled and converted* into deliverables.
- Processes are the key to providing a clear understanding of what an organisation does and the QCs it has in place to do those activities.

The Basic Quality Processes



Core Business Process

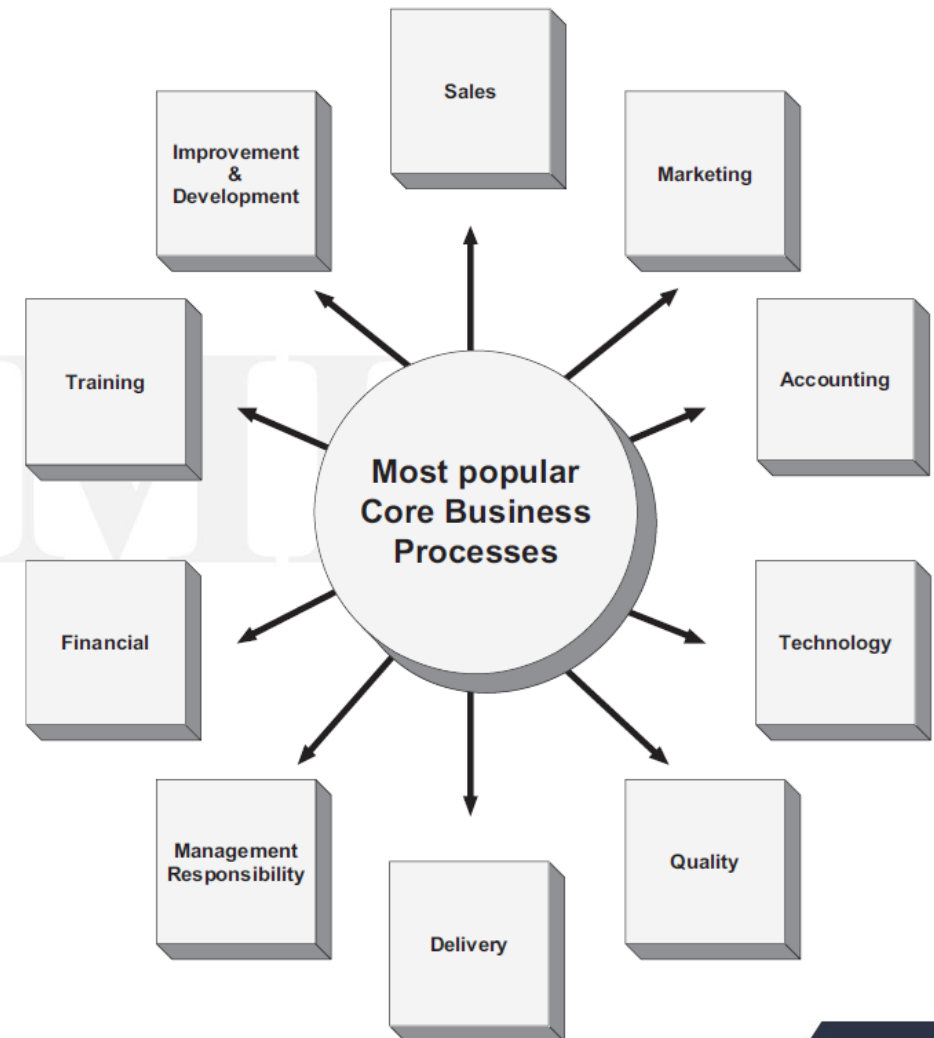
- The Core Business Process describes the **end-to-end activities** involved in **producing a contract deliverable** or **marketing opportunity**. It commences with the **definition of corporate policy** and ends when the **product or service is manufactured and/or marketed**, or the **service completed**.

What types of Core Processes would a business require?

- Sales & Marketing
- Accounting & Technology
- Quality & Products or Service Delivery
- Management, HR & Finance
- Product or Service Development.

When you start to grow, however, this will introduce new complexities that might require more employees and more focus, so these five processes will have to be expanded (e.g. sales and marketing might have to become two separate entities)

Most popular Core Business Processes



Supporting Processes

- A **process owner** with **full responsibility** and **authority** for *managing the process* and *achieving process objectives* should be nominated.
- The Core Business Process may then be **supplemented** (depending on the size of the business) by a number of **supporting processes** that *describe the infrastructure required to manufacture (or supply) the products and services on time.*
- it is **essential** that you define your **Quality Policy** and **objectives** for each **supporting process**.

Supporting Processes

Thus, for each process within the flowchart there will be accompanying documentation detailing:

- **Objective:** what the process aims to achieve;
- **Scope:** what the process covers;
- **Responsible owner:** who is ultimately responsible for implementing the process;
- **Policy:** what the organisation intends on doing to ensure quality is controlled;
- **Key performance indicators:** those items of objective evidence that can be used as a way of monitoring performance of the process;
- reference to supporting system documentation (i.e. QPs and WIs).

Supporting Processes

- All businesses revolve around taking inputs and putting them through a series of **activities** that turn them into useful outputs, be they products or services. These **activities** are the **supporting processes**.

ACEMI

Secondary supporting processes

Secondary supporting processes may include such items as:

- identification and provision of suitable Staff;
- management and support of Staff;
- identification and provision of information;
- identification and provision of materials;
- identification and provision of equipment and facilities;
- management of the QMS;
- continual improvement.

Sample Processes of an Organization



Sample ISO Process

نشان فرایند: فرایند مدیریت کیفیت		مالک فرایند: مدیریت عامل	
مأموریت فرایند: هدف گذاری، برنامه ریزی، سازماندهی، هدایت و راهبری شرکت، بازنگری سیستم مدیریت کیفیت در جهت اجراء و حفظ آن			
ورودی	از	فعالیت های مرتبط	خروجی
گزارشات عملکرد	کلیه فرایندها	تعیین خط مشی و اهداف سازمانی	خط مشی مصوب
گزارش عملکرد سیستم مدیریت کیفیت	بهبود	تعیین اهداف استراتژیک، برنامه های دستیابی و پیگیری حصول آن	اهداف مصوب
درخواست تخصیص منابع مورد نیاز	مدیریت پروژه	بازنگری سیستم مدیریت کیفیت	شرح وظائف و اختیارات مصوب
گزارش مطالعات بازار و بررسی های محیطی		تصویب شرح وظائف و اختیارات پرسنل	صورجلسه بازنگری مدیریت
گزارش نقاط قوت و ضعف داخلی سازمان	توسعه بازار	تعیین و اختصاص منابع مورد نیاز	مصوبات و دستورات مدیریت
		تعیین استراتژی ها و برنامه های بلند، میان و کوتاه مدت	استراتژی ها و برنامه های عملیاتی
		گزارشات عملکردی	گزارشات عملکردی
نحوه پایش و کنترل		منابع مورد نیاز	
• تشکیل جلسات بازنگری مدیریت • اعمال موارد مربوط به تصمیمات/صورجلسات • تشکیل جلسات کمیته راهبری به منظور بررسی پیشرفت برنامه ها		• نیروی متخصص، منابع مالی (در صورت نیاز) جهت اجرای پروژه های شرکت • برنامه های اصلاحی، منابع اطلاعاتی شامل محیط داخلی و خارجی	
شاخص های اندازه گیری			
عنوان شاخص	نحوه اندازه گیری	مقدار هدف	مقدار مجاز
میزان دستیابی به اهداف کیفی برنامه ریزی شده	$100 \times \frac{\text{تعداد اهداف کیفی محقق شده}}{\text{تعداد کل اهداف برنامه ریزی شده}}$ = میزان تحقق اهداف کیفی	۸۰ درصد	حداقل ۶۰ درصد
انتخاب استراتژی های مناسب در راستای چشم انداز شرکت	اثربخشی استراتژی های تدوین شده از نظر مدیران ارشد سازمانی	۹۰ درصد	حداقل ۷۵ درصد
در نظر گرفتن کامل و صحیح ورودی و خروجی های بازنگری مدیریت	تعداد عدم انطباق های یافت شده در این خصوص توسط ممیز شخص ثالث	صفر	حداکثر ۱ عدم انطباق جزئی

Process Mapping

- Process mapping is an essential technique for **identifying all the processes that take place in an organization** as well as **their interrelation** so that it is easy to **understand the sequence** at which these processes take place.
- A good process map should be a **high-level map** of **how** your organization **processes flow**, **showing inputs and outputs** and **how your production or service goes** from being input through each of the processes until it becomes the desired **output**.
- Each process on the process map should coincide with a process actually taken place in your organization, and be called and defined in the same way your organizations call it.

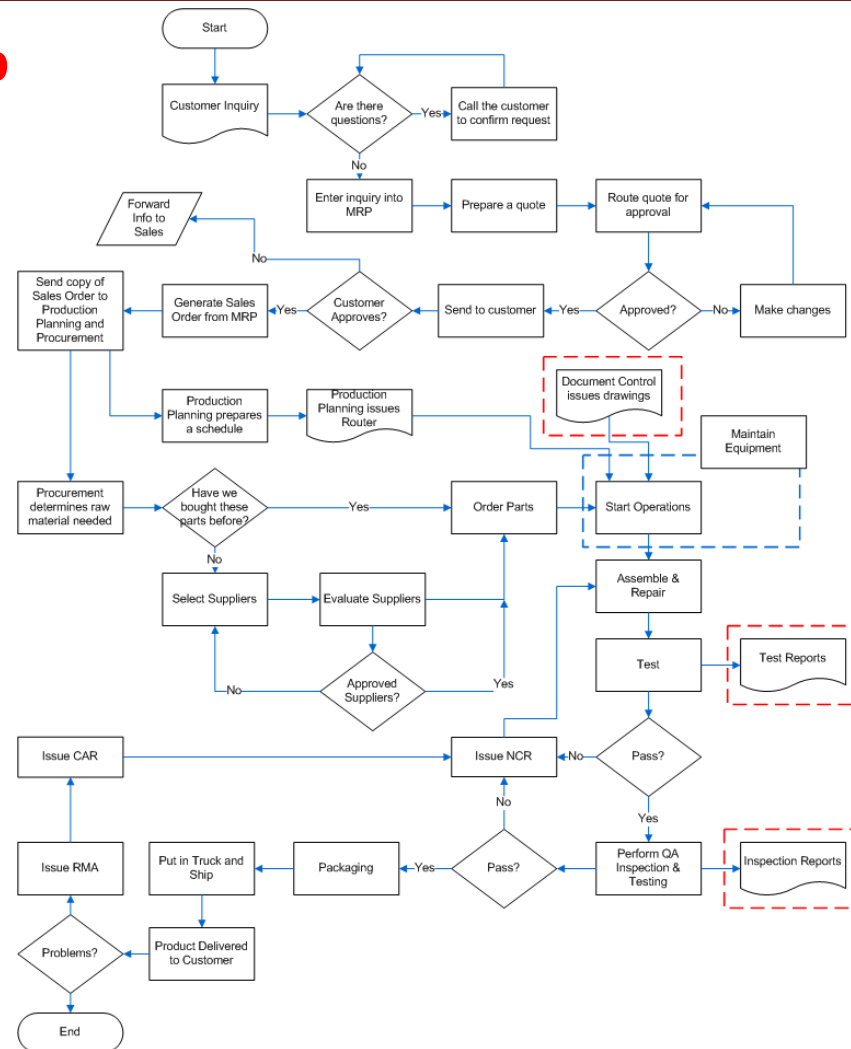
Process Mapping

- This is the defining moment that makes an organization unique, is the process mapping: even if two organizations make the same product, and perhaps have similar processes, ***their process maps will not look the same.***

The Process Approach

Session 1

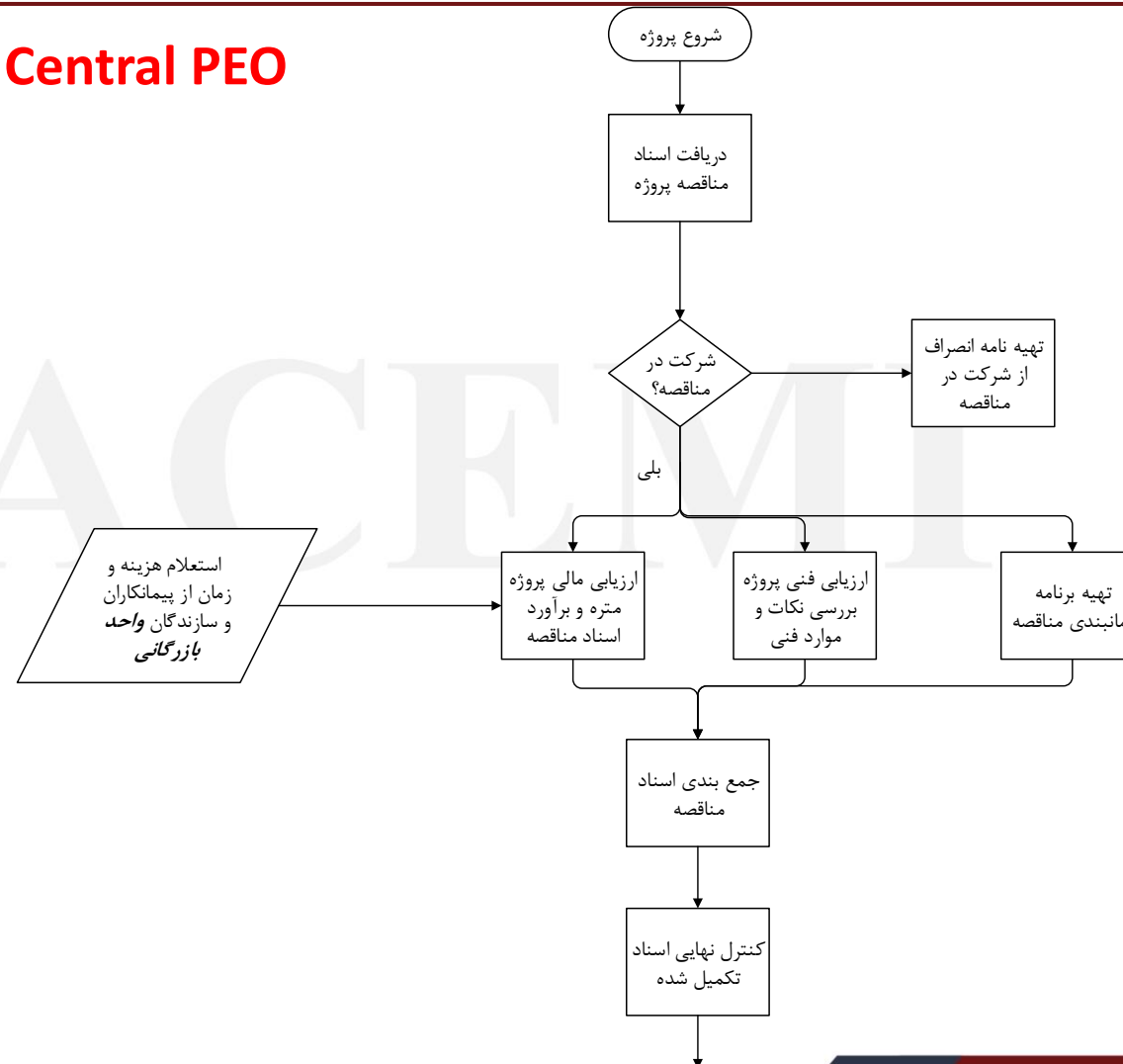
Sample Process Map



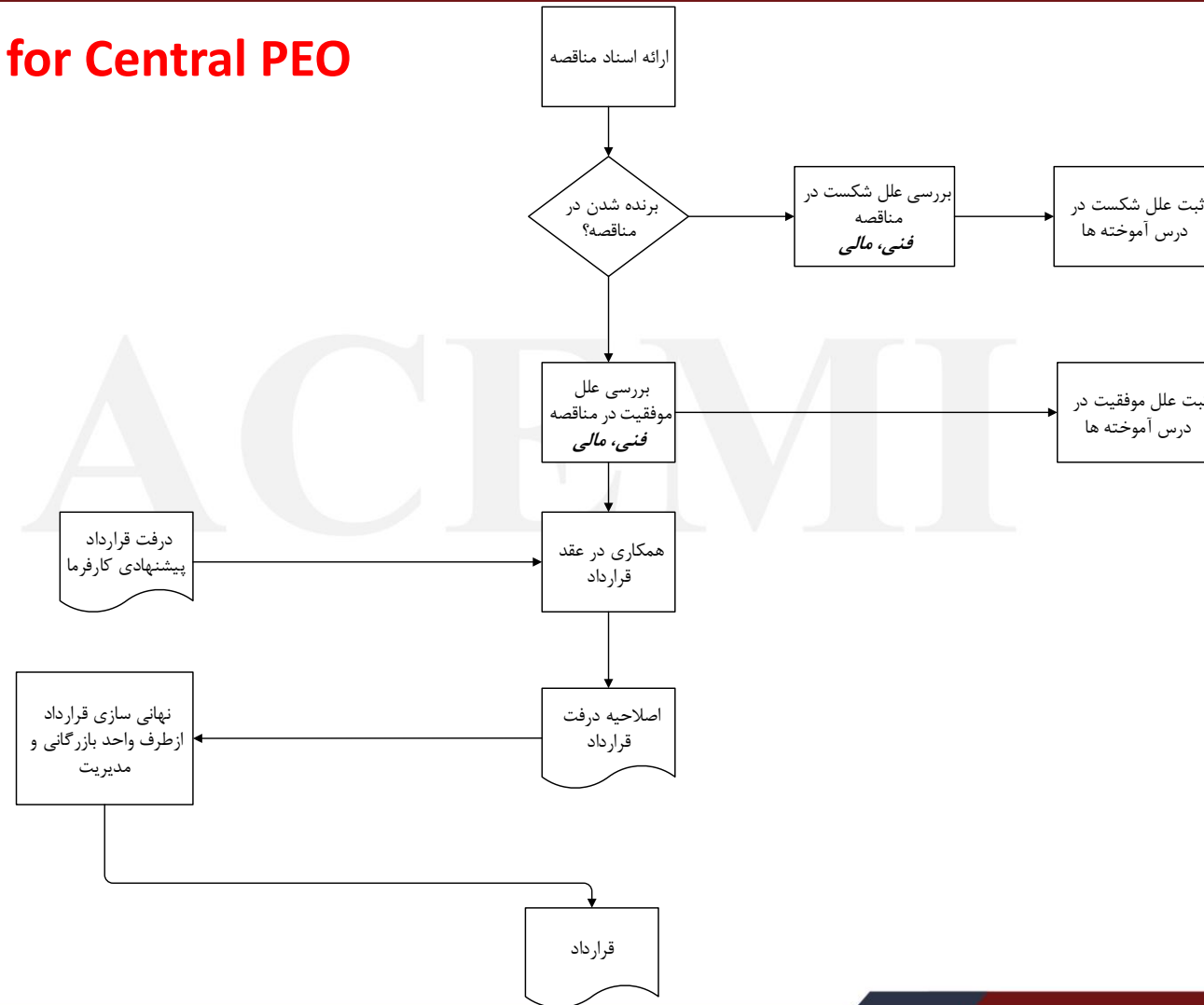
Basic Flowchart Shapes

	Process		Decision
	Subprocess		Start/End
	Document		Data
	Database		External Data
	Custom 1		Custom 2
	Custom 3		Custom 4
	On-page reference		Off-page reference

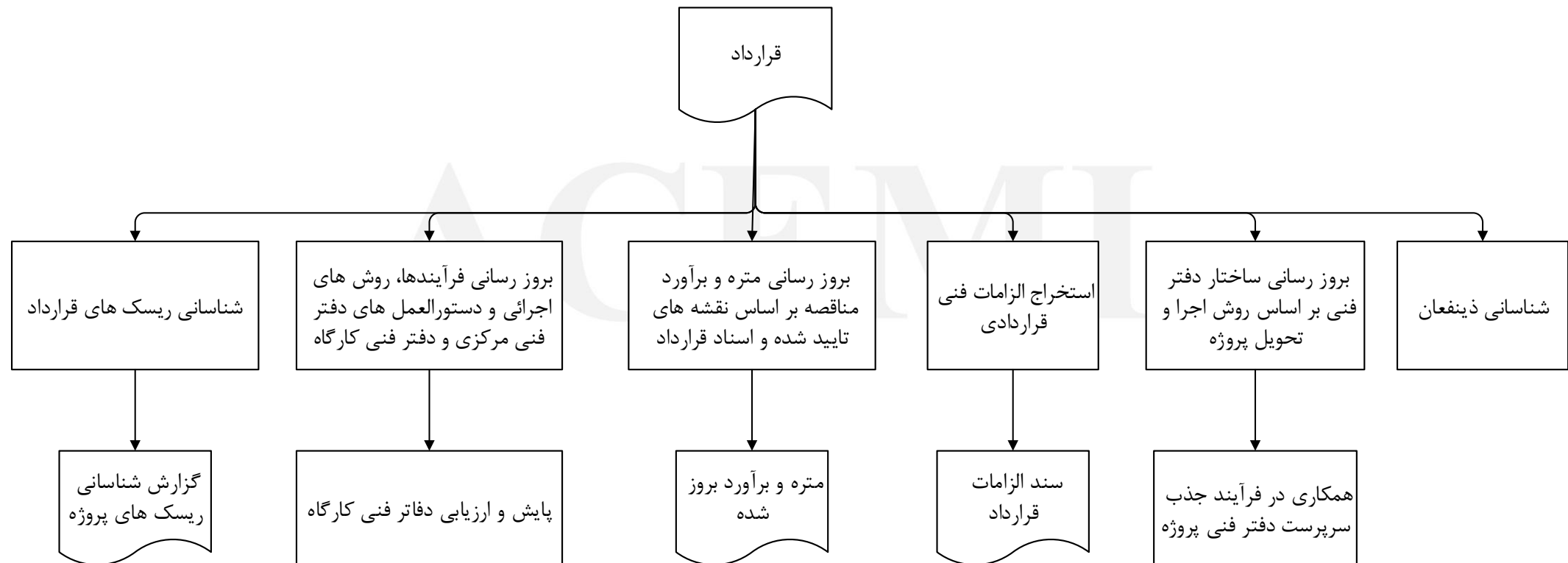
Sample Process Map for Central PEO



Sample Process Map for Central PEO



Sample Process Map for Central PEO



Inter-relationship of process documentation

All processes are documented to give a **complete picture** of **how to** perform the activity to a **consistent level of quality**. The level of detail varies depending whether it is a:

- **Process**: an outline of its objective, scope and key performance indicators;
- **Quality Procedure**: an enlargement of the process explaining how it is controlled;
- **Work Instruction**: the 'fine print' required to perform a specific activity.

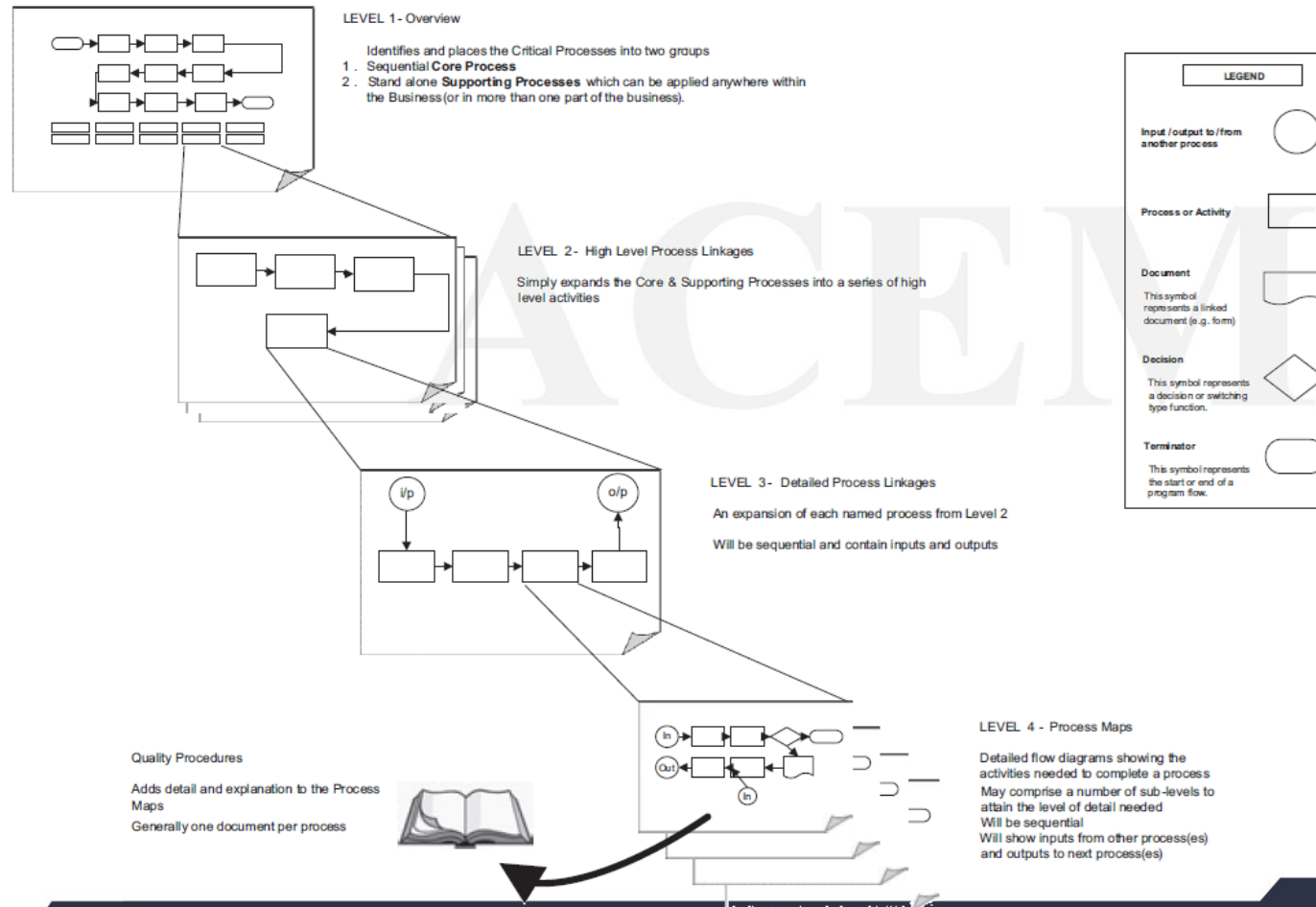
Inter-relationship of process documentation

- Throughout ISO 9001:2015, the **requirement for continuous improvement** is frequently (and heavily) **emphasised**. The following process model clearly shows how the six major sections (i.e. leadership, planning, support, operations, performance and improvement) of ISO 9001:2015 inter-relate and how the improvement processes continuously revolve around all other aspects of Quality Management.

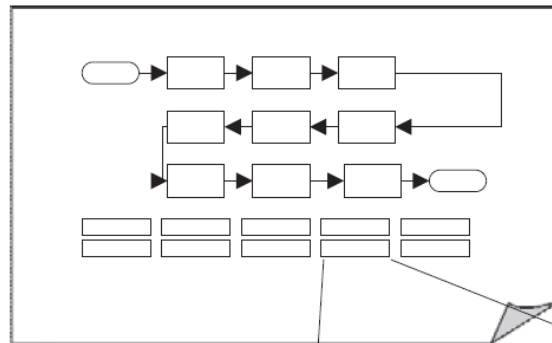
The hierarchy of processes

- When developing process maps, they can become very complex. It is therefore recommended that you develop **a hierarchy of process maps**, which enables users to 'drill down' through a number of levels to reach the **desired level of detail**, and figure in the next page shows one way in which this can be achieved.
- **Level 1 (i.e. The Overview)** does nothing but show a **summary of the Core Business Process and the supporting processes**.
- Should you wish to know more detail on a certain process, then by drilling down to the **Level 2 (High Level Process Linkages)** maps you can get more information on the activities making up that specific process.

The hierarchy of processes



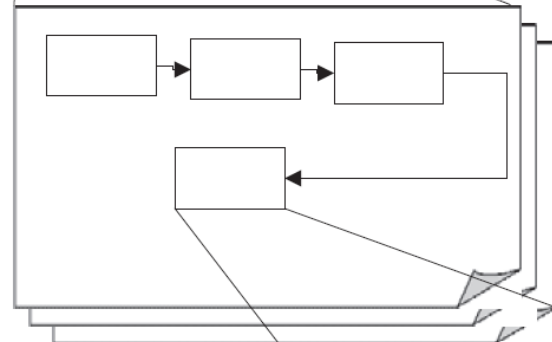
The hierarchy of processes



LEVEL 1 - Overview

Identifies and places the Critical Processes into two groups

1. Sequential **Core Process**
2. Stand alone **Supporting Processes** which can be applied anywhere within the Business (or in more than one part of the business).

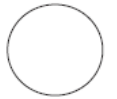


LEVEL 2- High Level Process Linkages

Simply expands the Core & Supporting Processes into a series of high level activities

LEGEND

Input / output to/ from another process



Process or Activity



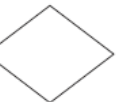
Document

This symbol represents a linked document (e.g. form)



Decision

This symbol represents a decision or switching type function.



Terminator

This symbol represents the start or end of a program flow.

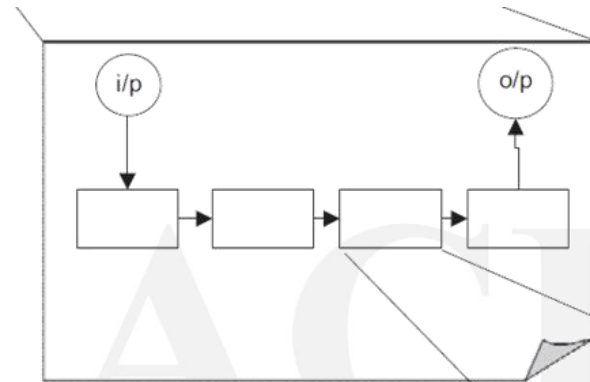
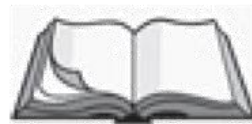


The hierarchy of processes

Quality Procedures

Adds detail and explanation to the Process Maps

Generally one document per process

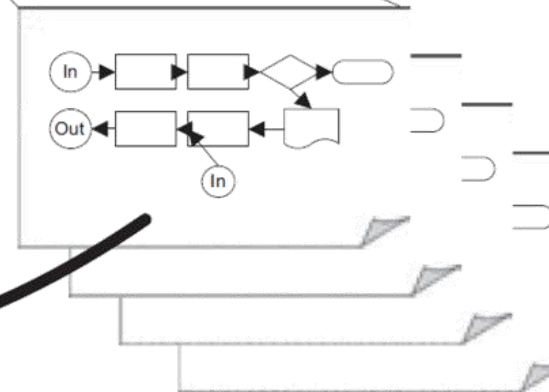


LEVEL 3- Detailed Process Linkages

An expansion of each named process from Level 2

Will be sequential and contain inputs and outputs

This symbol represents the start or end of program flow.



LEVEL 4 - Process Maps

Detailed flow diagrams showing the activities needed to complete a process
May comprise a number of sub-levels to attain the level of detail needed
Will be sequential
Will show inputs from other process(es) and outputs to next process(es)

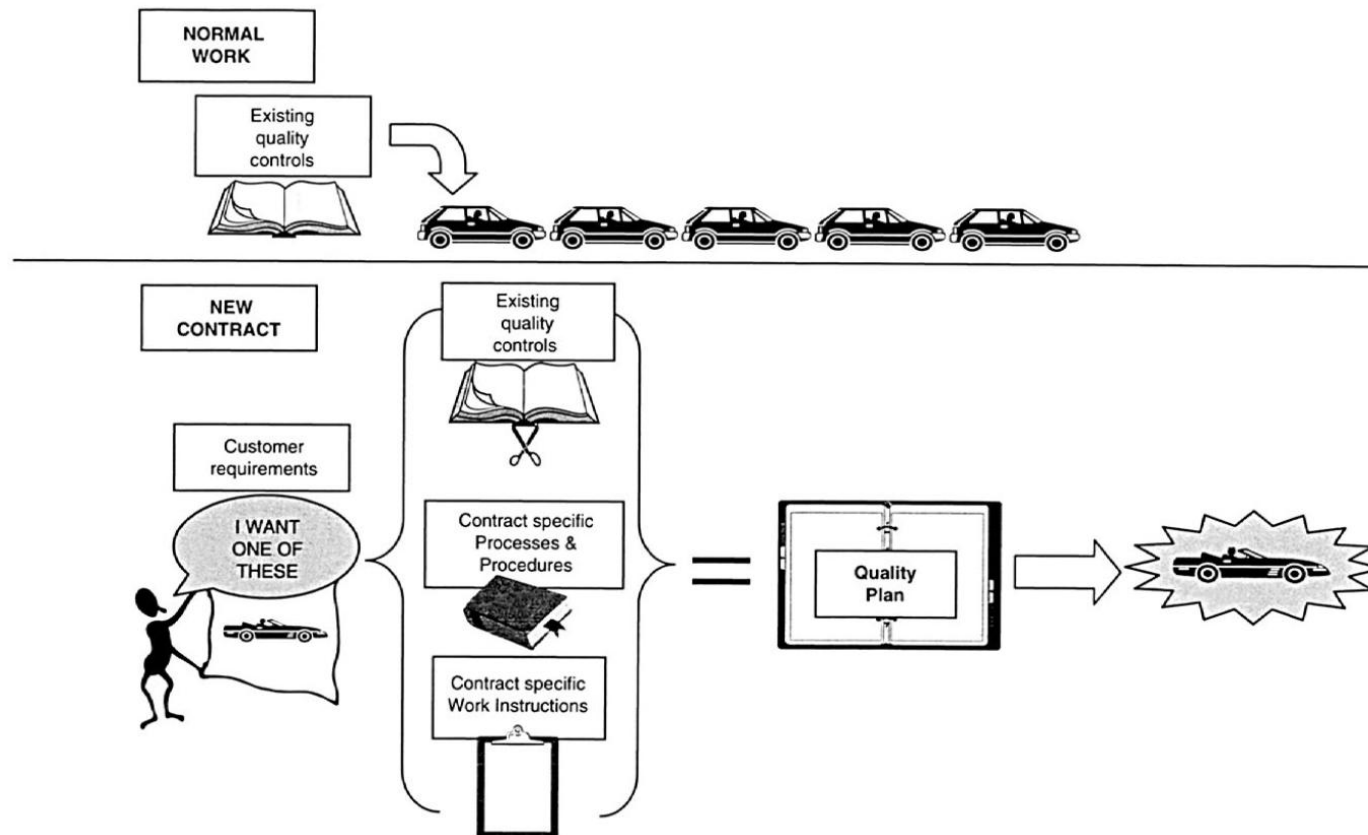
The hierarchy of processes

- This type of hierarchy is **ideal** for producing *computer-based management systems*, where the functionality offered by websites *enables process maps to be linked*, thereby **simplifying** navigation between maps.

WHAT IS A QUALITY PLAN?

- A quality plan is a document, or several documents, that together specify **quality standards, practices, resources, specifications**, and the **sequence of activities** relevant to a **particular product, service, project or contract**. They are used to record the **quality requirements** for their activities and to monitor and assess adherence to their req
- You may already have QCs for your normal product or services, but what do you do if someone wants something completely different? You could simply apply your existing QCs, but it is unlikely that they will cover any eventuality. What you need is ***a Quality Plan to address the specific requirements of that particular contract*** and which are a ***true record of the customer's requirements***.

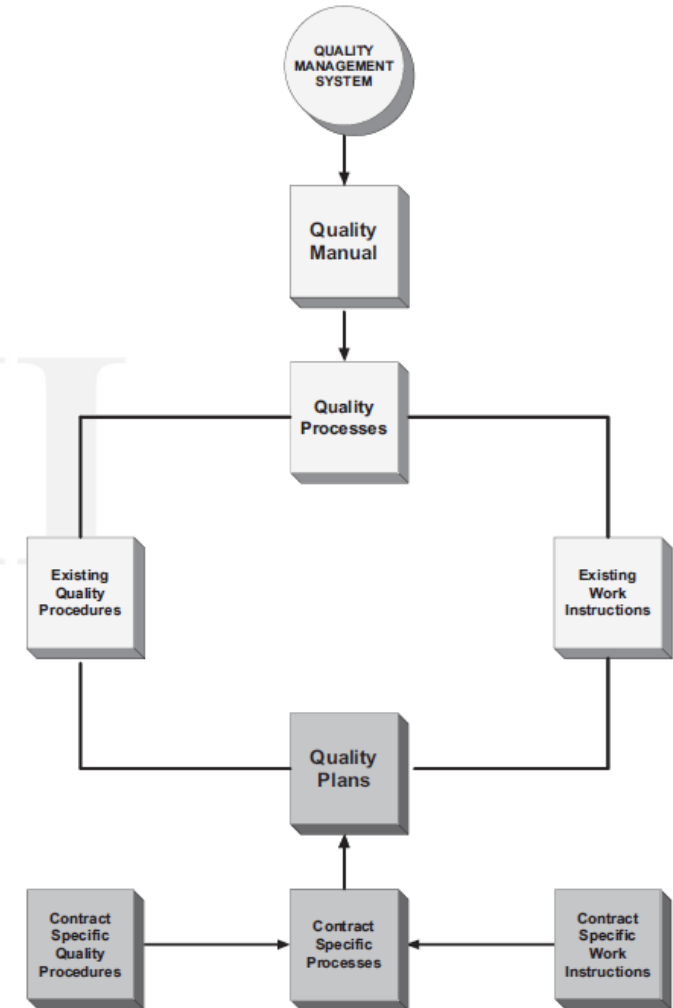
QUALITY PLAN



Quality Plans are needed to control the quality of specific projects

QUALITY PLAN

- A Quality Plan supplements the organisation's existing QMS.
- In essence, Quality Plans provide a collated summary of the requirements for a specific project.
- They will cover all of the quality practices and resources that are going to be used, the sequence of events relevant to that project, the specific allocation of responsibilities, methods, the QPs and WIs, together with details of the testing, inspection, installation (if required) examination and audit programme stages.



QUALITY PLAN

A **well-thought-out** Quality Plan will divide the project into stages, show **what type of inspection has to be completed** at the **beginning, during** or **end** of each **stage** and indicate how these details should be recorded. The Quality Plan should be planned and developed in conjunction with **design, development, manufacturing, subcontracted pre- and post-installation** work and ensure that all functions have been fully catered for.

What should be covered by a Quality Plan?

One of the main objectives of quality planning is to identify any **special** or **unusual requirements, processes** and **techniques** (including those requirements that are unusual by reason of **newness, unfamiliarity, lack of experience** and/or **absence of precedents**). As pointed out in ISO 9000, if the **contract specifies** that a **Quality Plan is required**, then that Quality Plan should **fully** cover the areas listed in this figure.

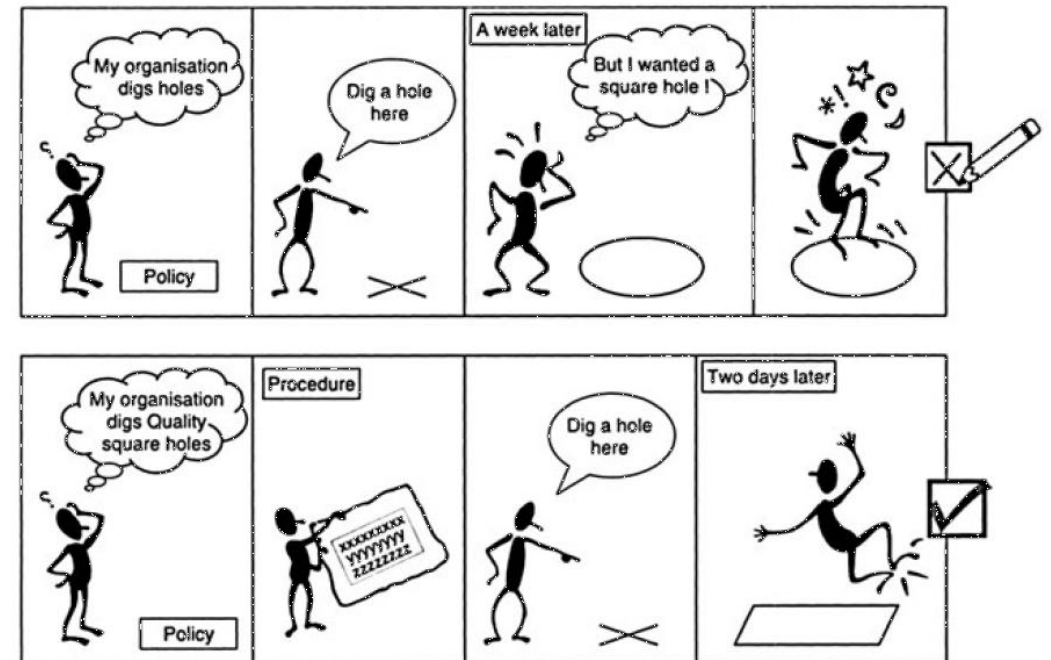


What should be covered by a Quality Plan?

- **ISO 10005** (Quality Management Systems – Guidelines for Quality Plans) provides useful guidance on how to produce Quality Plans, as well as including helpful suggestions on how to maintain an organisation's quality activities.

WHAT IS A QUALITY PROCEDURE?

- Quality Procedures are used to **implement the quality processes** of an organisation. QPs **detail what has to be carried out** to meet the requirements of these primary and secondary processes and their associated Quality Policies.



WHAT IS A QUALITY PROCEDURE?

- Think of QPs as **clear, concise instructions**.
- It is essential that ***all*** QPs are **written down** so that **everyone knows what to do**.
- It is **not mandatory** to write procedures for **everything**.

What is the best way to write a Quality Procedure?

- A simple rule is don't bother unless you really **have to**.
- A degree of **common sense** must prevail when writing procedures, and you should always consider the **known competency** and **knowledge** of the **personnel performing them**.
- If you employ highly skilled professionals, it would be foolish to spend hours writing a procedure on something which they are already qualified to do or for which standards and guidelines already exist.
- On the other hand, you will probably want to write a procedure where you use **untrained Staff** to perform it.

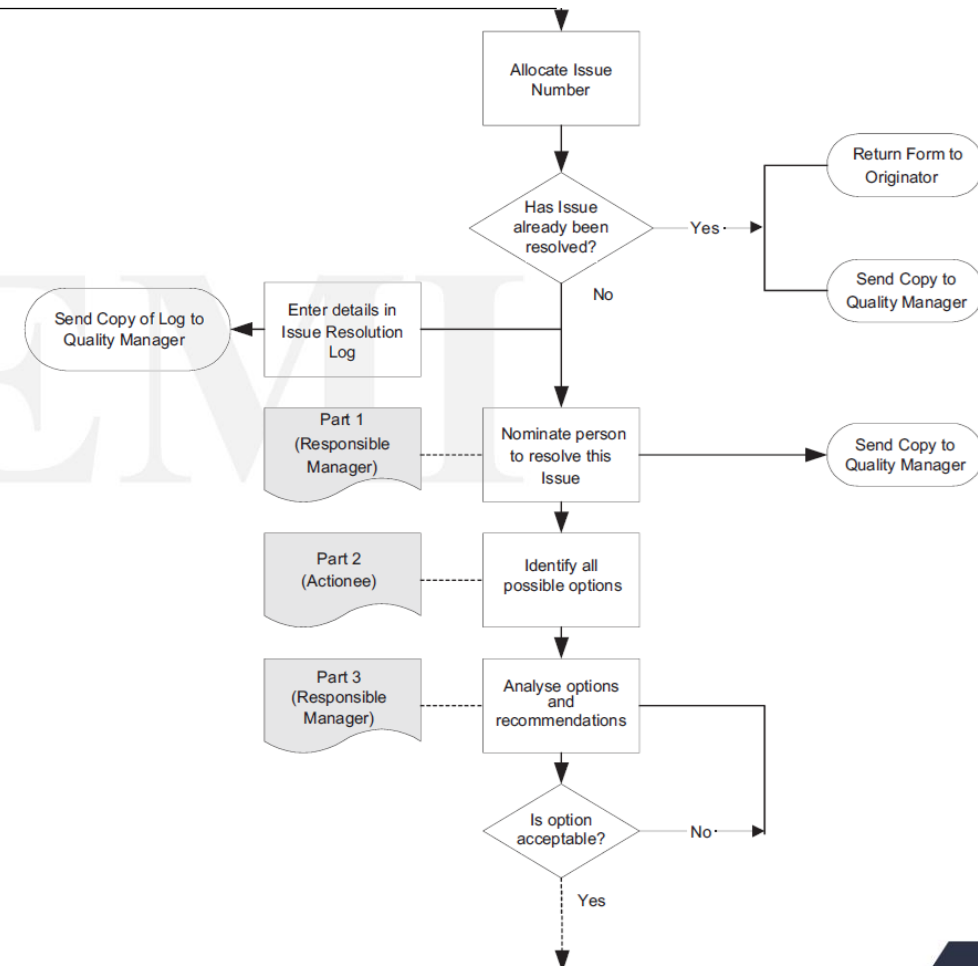
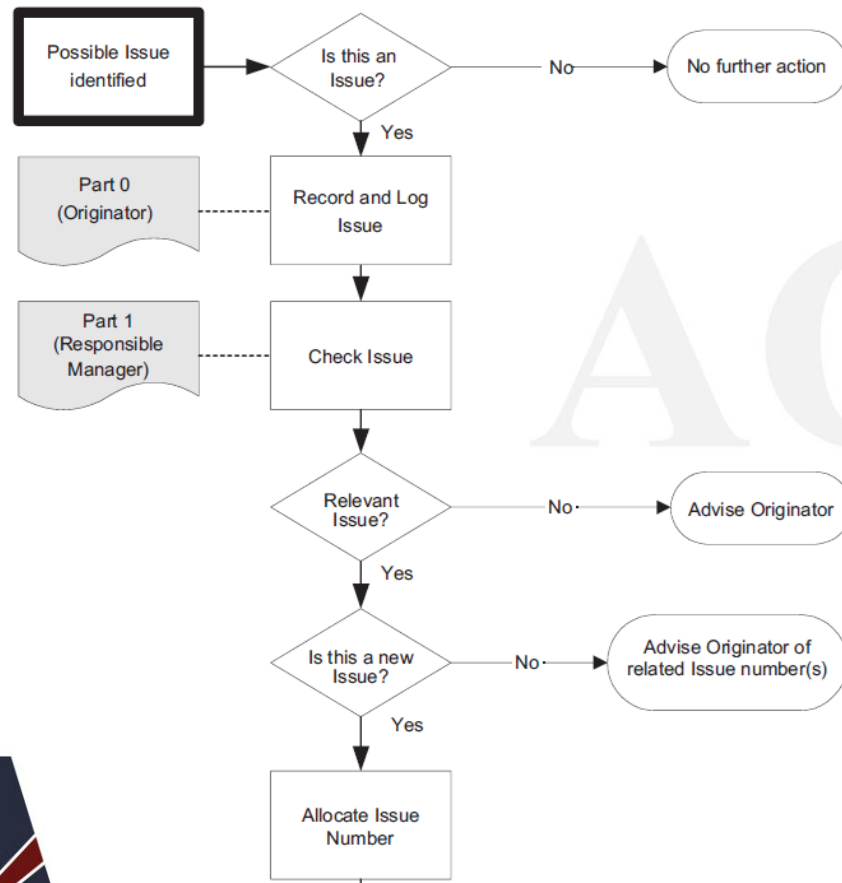


A simple rule is: ***don't bother unless you really have to.***

What is the best way to write a Quality Procedure?

- An easy-to-follow flowchart can be enhanced with explanatory text so that the entire process is clearly understood and easily trained. The benefit of flowcharts is that they can be **stuck up on notice boards** so that the people who have to implement the procedure can readily see what they are expected to do.

A typical Quality Procedure flowchart



What goes into a Quality Procedure?

QPs will mainly include (but are not limited to) the following:

- **Document data sheet:** all the salient information about the document – file name, who wrote it, a summary of the contents, when it was approved, who approved it, etc.;
- **Distribution list:** a record of everyone who has a controlled copy of the document;
- **Amendments:** a record of all changes made to the document;
- **Contents list:** a list of all the chapters, sections, parts and annexes, etc. that make up this document;

What goes into a Quality Procedure?

- **List of annexes:** all parts of a document should be traceable, especially when they are in separate volumes;
- **List of illustrations/tables:** a list of all the figures and tables included in the document;
- **Abbreviations** and acronyms: an explanation of any abbreviations or acronyms used in the document;
- **Terminology:** an explanation of any technical or confusing terminology used in the document;
- **References:** any reference material that is specifically referred to in the document;

What goes into a Quality Procedure?

- **Scope and objectives:** this should list why you need the procedure, what it is for, the area covered and any exclusions.
- **Procedure overview and procedure:** this is the main part of the document and details in clear, concise and unambiguous terms the actions and methods to be used. Ideally the procedure should be detailed in a logical order with the aid of flowcharts;
- **Responsibilities:** clear specifications of who is responsible for implementing the procedure and who can carry it out including (if necessary) minimum training requirements;
- **Relevant forms:** the identification of any forms, paperwork or computerized forms required to implement the procedure.

WHAT IS A WORK INSTRUCTION?

- *WIs describe, in detail, **procedures** such as ‘what is to be done’, ‘who should do it’, ‘when it should be done’, ‘what supplies, services and equipment are to be used’ and ‘what criteria have to be satisfied’. These WIs should be regularly reviewed for their continuing acceptability, **validity** and **effectiveness**.*
- Instructions provide direction to various ISO 9000 levels of personnel. They also provide criteria for **assessing** the **effectiveness** of **control** and the **quality** of the **material**, ensure **uniformity** of **understanding**, performance and continuity when personnel changes occur. They provide the basis for **control**, **evaluation** and **review**’.

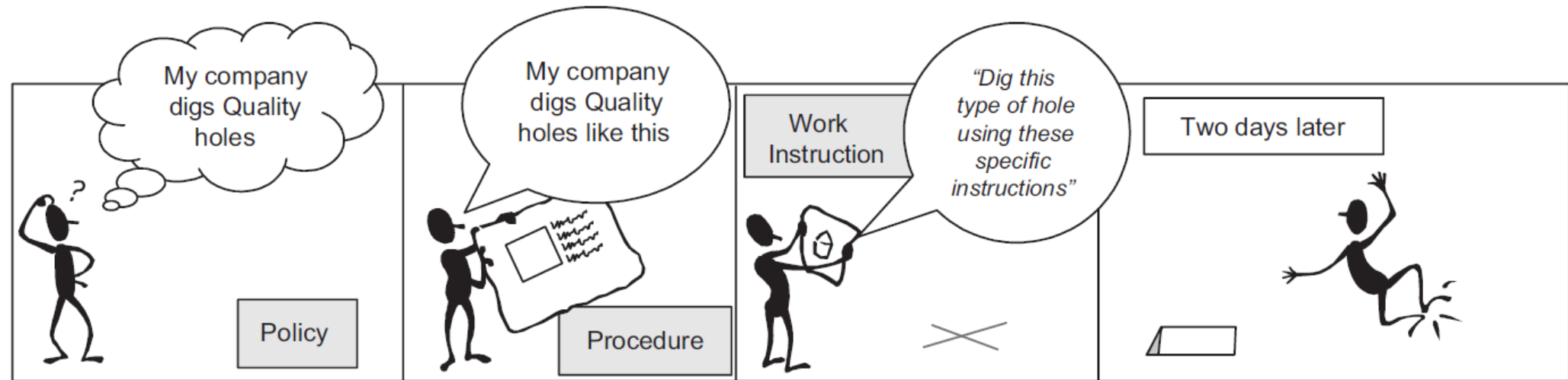
WHAT IS A WORK INSTRUCTION?

- Although ISO 9001:2015 states that Work Instructions (WIs) are ***no longer required*** (they now refer to them as '***documented information that defines the activities to be performed and the results achieved***'!), it seems nowadays that whenever you purchase something that you will need to assemble yourself (e.g. a fruit cage) or use (e.g. a simple car Hoover) a WI is included in the packing box. So whatever you call this – a WI or 'written guidance' – ***it is still part of the overall Quality Assurance chain*** – in my opinion.

In a nutshell:

- Procedures: tell you ***who does what and when***;
- Work Instructions: tell you ***how to do something at a more granular level***.

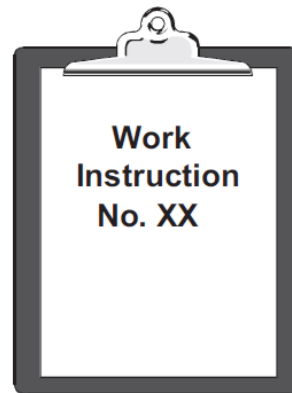
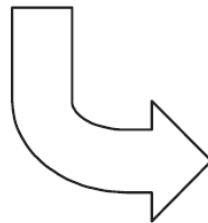
WORK INSTRUCTION



Written instructions should leave no room for error

What should go into a Work Instruction?

Document Data Sheet
Distribution List
Contents
References
Procedure
Responsibility
Relevant Forms
Scope & Objectives



What should go into a Work Instruction?

- **Document data sheet:** all the salient information about the document – file name, who wrote it, a summary of the contents, when it was approved, who approved it and a record of all changes made to the document etc.;
- **Contents list:** a list of all the chapters, sections, parts and annexes, etc. making up this document;
- **List of annexes:** all parts of a document should be traceable, especially when they are in separate volumes;
- **References:** a clear reference to any material or technology that is specifically referred to in the document. Also any associated QPs, etc.;

What should go into a Work Instruction?

- **Scope and objectives:** this should define exactly what the WI is needed for. Normally this is a very simple statement because a WI would usually be limited to one process (e.g. the WI illustrated in Fig. 2.48 detailing the actions to be taken to dig a square hole);
- **Procedure:** again, referring to Fig. 2.48 as an example, this will state the manner of production, installation or application where the absence of such controls would adversely affect the quality of the hole to be dug using hand shovels only, and would require temporary shoring to prevent collapse. Consideration should also be given to any safety implications that may exist when carrying out the process;

What should go into a Work Instruction?

- **Responsibility:** the WI must clearly state who can carry out the process;
- **Relevant forms:** the identification of forms – hardcopy or computerised –required to implement the WI.

ACEMI

Samples

- Quality Manual
- Quality Plan
- Quality Processes
- Quality Procedure
- Work Instructions
- Forms

با تشکر از صبر و حوصله شما

راه های تماس مستقیم

Email : Shahinebrahimi.pm@gmail.com

LinkedIn: www.linkedin.com/in/shahinebrahimi-pmp

Instagram : Shahin-ebrahimi62

Tel : 09102369670 - 09181734470

dralavipour.com



با ما همراه باشید موسسه مهندسی و مدیریت ساخت علوی‌پور			
+۹۸ ۲۱ ۴۶ ۱۰۰ ۴۴۵		+۹۸ ۲۱ ۴۶ ۱۰۰ ۴۵۰	
info@dralavipour.com		ACEMI	
ACEMI_social		Alavipour_pm	
ACEMI_channel		Alavipour_pm	