SAPPMA Quality Workshop

advanced laboratory SOLUTIONS

Co-presented by Reza Theunissen and Khanya Ngobo
Product Specialists, Instron and TA Instruments

Ian Venter

10-04-2019

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SAPPMA Quality Conformance and Auditing

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Conformity assessment VS Conformity Control

- Conformity assessment. Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled (ISO/IEC Guide 2).
- Conformity control. Ensuring that products remain conforming once they have been certified as conforming.

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Resources needed to determine conformity

- The resources needed to determine conformity might be considerable; gauges, test equipment, specialist skills and knowledge and therefore rather than equip every worker with the means to determine conformity, the task is managed by a separate group of dedicated specialists. In effect these specialists support the worker and allow the worker to make the judgement on acceptability. But when this judgement remains with the specialists it again removes the worker's right to self-control.

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Challenges with QMS

- ISO 9001 has led organizations creating a position in their management structure that responded to the standard. It often starts off with the appointment of an ISO 9000 project Manager or Coordinator who works with the consultant to document the system through to certification. Thereafter this person manages the system and possibly acts as the management representative or works for such a person. There is indeed a need to develop a management system, maintain and improve it but that job is the responsibility of the whole management team. If they choose to assign this responsibility to another, that is their choice, but it is an approach that is flawed because the management system is the way the organization functions and to make anyone other than the CEO responsible would be illogical.
- What this person often results in doing is maintaining the manuals, processing change requests on documents and managing the quality audit programme. This tends to place all the system documents under the control of one person or department which is not healthy because it inevitably leads to situations where the documentation is always lagging behind actual practices. The internal audits pick up these issues and Quality System Department then spend most of their time chasing paper and not tending to real quality problems.

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Possible opportunities in QMS

- There is a role at the centre of an organization for a systems specialist who assists managers in developing, maintaining and improving processes so that they interact in ways that achieve the desired outcomes. The role would be enhanced by the addition of the system audit function thus providing data with which to identify opportunities for improvement without removing the responsibility for performance, efficiency and effectiveness from the individual managers.

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Conformance

- The dimension of conformance depends to what extent a product's design and operating characteristics meet established standards.
- All products and services involve specifications of some sort. When products are developed, these specifications are set and a target is set, for instance the materials used or the dimension of the product. Not only the target but also the tolerance (the range of permitted deviation from the target) is defined.
- Different approaches to measuring quality exist. One is measuring a simple conformance to specifications; the other is measuring the degree to which parts or products deviate from the ideal target when it is measured.

SAPPMA Quality Auditing

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Results Driven Audits

- 1. Firstly look at **what results** are be being achieved **relative to the organization's declared objectives**,
- 2. Establish **whether these results are consistent with the intent** i.e., consistently conforming product, satisfied customers, compliance with relevant statutes and regulations and continual improvement.
- 3. **Discover what processes are delivering these results**.
- 4. Determine **whether these processes are delivering these results**. (refer to Process Audits)
- 5. Lastly check that **what is being done demonstrated conformity** with the requirements of your organisation.
- In many cases, it may, may not be possible to get beyond Step 1 simply because the organisation cannot demonstrate what it is achieving as **there is no simple way of showing performance**.
- Secondly, it might **not be possible to separate the objectives of masses of data** the organization presents and therefore not get beyond Step 2.
- However, once a results-driven audit has been completed and all deficiencies resolved (which may take a considerable time relative to other audits) subsequent audits will be a fraction of the time. If there has been no change in the organization's objectives and no adverse change in its performance when Step 2 is completed, the system remains compliant and all therefore there is no justification for checking conformity at such a high frequency
- If there are changes that will affect the integrity of the system, an analysis needs to be carried out to establish the impact of these changes and repeat steps 1-5 above on the process affected by these changes

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Auditing for effective implementation and maintenance

Standards require the organization to conduct **internal/external audits at planned intervals** to **determine** whether the **quality system is effectively implemented and maintained**.

- What Does this Mean?
- **Effective implementation should not be confused with system effectiveness**. The evaluation of **system effectiveness serves to explore better ways of doing things**, whereas, an **evaluation of effective implementation serves to explore whether the processes are being run as intended and delivering the required outputs**, i.e., people are **doing what they are required**, and the **results are having the desired effect**. A process may be run as intended but not achieve the desired results indicating a design weakness in the process.
- **Effectively maintained** means that the **processes continue to remain capable** despite changes in the quantity, condition or nature of the human, physical and financial resources.
- In the past it has been **assumed that if people were found to be following the as documented**, the **system** was **effective**. Conversely, if the people **were not found** to be following the procedure the **process was somehow ineffective**. But this was not the reason for the system i.e. it was not the purpose of the **system to force people to follow procedures**. The **purpose was to ensure results**, therefore a **system is effective** only if it can be **demonstrated that the desired results are being achieved**.

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Auditing for effective implementation and maintenance

Why is this Necessary?

- The requirement responds to the Factual Approach Principle.
- In order to manage the organization/order effectively, it is necessary to know whether the system for achieving the standard /organisation objectives does the job for which it has been designed.
- Management also needs a system that does not collapse every time something changes - the system must be robust. It must cope with changes in personnel changes in customer requirements, changes in the environment and in resources.
- Consequently, to remain robust the system has to be effectively maintained.

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Auditing for effective implementation and maintenance

How is this Demonstrated?

- The management system comprises a series of interacting process and each contributes to its overall effectiveness.
- This requirement can be met in one of three ways:
- • by system implementation audits;
- • by process audits conducted by personnel external to the process: and
- • by process audits conducted by personnel operating the process.
- System Implementation Audit
- There are two ways for conducting the system implementation audit:
- • by planning a series of audits that will cover the entire system in one cycle;
- • by analysing the results of process audits and determining effectiveness by correlation.
- If the system implementation option is chosen, you should not need to build into each process an audit mechanism. The analysis option is only an option when each process has a build-in audit mechanism.

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Auditing for effective implementation and maintenance

- **Process Audit**
- The traditional practice has been for processes to embody processes to embody provisions for product measurement and process monitoring that is results-oriented. The measures are related to what is being processed – not the extent to which the rules are being followed. The internal audit has taken on this role, but it misses the crucial question of establishing the efficiency of the process. Results were not matched with the effort used to produce them.
- A process is not efficient if it achieves the required results by wasting resources
- It is therefore necessary to periodically examine whether:
- • the activities are being performed as planned;
- • the resources are being effectively utilized.
- Such audits would examine activities not only to verify that the prescribed actions and the decisions have been taken but also to verify the time and effort taken to perform them.
- The plans and specifications should define targets for time and effort so that the audit is against agreed targets and does not become a witch-hunt. The audits could be performed by personnel external to the process, such as internal auditors or managers or in fact by the supervisors of the process.

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Auditing for effective implementation and maintenance

- If we assume the system has been developed along the lines that the business and work process to be audited will be those the organization manages in order to satisfy its stakeholders.
- On this premise you would take the following steps in conducting a process audit:
- 1. Identify the agreed process outputs, measures and targets
- 2. Identify the key stages of each process on which delivery of these outputs depend
- 3. Establish for each stage that:
- a) The outputs, measures (or indicators) and targets of each stage have been defined and are consistent with the process outputs (i.e., they are leading and not lagging measures);
- b. The activities being carried out are those necessary to deliver the stage outputs and are consistent with the prescribed policies and procedures;
- c. The materials and equipment being used are those that have been specified and are being used under controlled conditions;
- d. The competences required to produce the stage output have been specified and that the competency of those producing these outputs has been assessed under controlled conditions and found acceptable;
- e. The information being used to produce the stage outputs is that which has been defined and that it is being used under controlled conditions; and
- f. Reviews are carried out to establish whether the stage outputs are being controlled and are meeting the targets.

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Auditing for effective implementation and maintenance

- 4. Establish that the provisions made for preventing failure such as error proofing are being effective.
- 5. Establish that process performance is being measured using the agreed indicators, that results are being recorded and reported and that appropriate action is being taken when targets are not met.
- 6. Establish that the methods of measurement are soundly based and consistent with the accuracy and precision required for the process outputs.
- 7. Establish that reviews are carried out to determine whether there are better ways of delivering the process outputs and that recommended improvements have been implemented or planned.
- 8. Establish that reviews are carried out to verify the relevance of the process outputs, measures and targets to current stakeholder needs and that changes have been implemented or are planned.

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Auditing for effective implementation and maintenance

- The various activities specified by the planned arrangements should result in an output that conforms in full with the specified requirements. However, there is variation in all processes and although the processes may be deemed capable, incidents can occur that escape detection. The product audit is performed to verify that output emerging from the process meets the specified requirements and therefore determines whether the controls in place are effective. Errors that are detected indicate that the controls are not effective as they should have been removed before output was released.

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Auditing for effective implementation and maintenance

- As product audits are performed to verify that the planned controls have been effective it follows that some policy decisions need to be taken regarding:

- When products audits are to be carried out - often this is after product release before shipment. However, product audits are also appropriate on products returned from customers;
- Who is to perform product audits - often this is a group independent of production so as to be unbiased or having freedom of action and decision;
- What the sampling criteria are to be – often this might be 1 in 10, 1 in 100.1 in a 1000 etc. depending on the production rate and product complexity;
- What happens to the batch from which the sample is taken while the audit takes place - often the batch is held pending the results of the audit;
- What the acceptance criteria are to be – these must address the same characteristics as specified by the customer with the agreed limits. It might be necessary to operate the product under actual or simulated conditions in order to measure some of the characteristics. However, some characteristics might not have been specified for manufacture such as the degree of surface abrasions to be expected from a crankshaft that has run 24 hours under a specific load. Some additional criteria might be therefore needed.

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Auditing for effective implementation and maintenance

- Clearly it might be necessary to develop strip down instructions because it may not be appropriate to simply reverse the assembly instructions. Forms will be needed on which to record the measurements and any observations such as unexpected wear marks, contamination, parts incorrectly oriented, parts missing, low torque etc.
- Product auditors need to be extremely vigilant. It's a job for an analytical person - someone who is not daunted by tedium, repetition and attention to detail and it needs to be a person who is cautious, intellectual, works slowly and is good at problem solving. Never put the product auditor under pressure - if you do you will encourage him or her to miss something important. There is no point in employing product auditors and ignoring the results. You will probably want to put some of your best people onto this job.
- Documenting the evidence is vital simply because someone or something created it and that someone or something is still around and may be creating more of it as the report is written. In the modern world of digital photography, here is a tool that seems designed for product auditors. It costs virtually nothing to capture exactly what was observed and even date the picture so there is no doubt. But because its easily done, can be overdone.
- Traceability is important also. The report should provide enough information to identify all products produced in the same batch and likely to possess the same characteristics. If you can't isolate all related products you run the risk of releasing suspect nonconforming product to users.

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Auditing for effective implementation and maintenance

- Regarding the effectiveness of the management system, the very existence of a document is not evidence of its effectiveness, but it could be regarded as a record. To be a record, the document would need to contain results of an examination into the effectiveness of the system,
- One can demonstrate the effective operation of the management system in several ways
- • by examination of audited results against the organization's objectives;
- • by examination of customer feedback;
- • by examination of system, process and product audit results;
- • by examination of the management review records;
- • by examination of quality cost data.
- **Showing records that every requirement of the standard has been met will not demonstrate that the system is effective**. You may have met the requirement but not carried out the right tasks or made the right decisions. The effectiveness of the management system should be judged by how well it fulfils its purposes

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Understanding of Product Audits

- There may be an entry on a computer database showing that an order has been placed with a particular supplier. So how would you ensure the adequacy of purchasing requirements in such circumstances? There follows a number of steps you can take:
  - Provide buyers with read only access to approved purchasing data in the database.
  - Provide buyers with read only access to a list of approved suppliers in the database.
  - Provide a computer file containing details of purchasing transactions with read and write access.
  - Provide a procedure that defines the activities, responsibilities and authority of all staff involved in the process.
  - Train the buyers in the use of the database.
  - Route purchase requisitions only to trained buyers for processing.
- The above approach is suitable for processing routine orders, however, where there are nonstandard conditions a more variable process needs to be developed.
- VERIFICATION OF PURCHASED PRODUCT
- Ensuring Purchased Product Meets Requirements
- The standard requires the organization to establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

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Understanding of Product Audits

- VERIFICATION OF PURCHASED PRODUCT

What Does this Mean?

- Verification is one of the fundamental elements of the control loop and in this case the verification serves to ensure that the output from the purchasing process meets the purchasing requirement. Verification may be achieved by several means before or after product is delivered or by building confidence in the source of supply so that product may enter the organization without any physical inspection. The requirement does not state when such verification should be performed and clearly it can be before, during and after receipt of the product. The standard leaves it to the organization's discretion to choose the timing that is appropriate to its operations,

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Understanding of Product Audits

- VERIFICATION OF PURCHASED PRODUCT
  - Why is this Necessary?
  - This requirement responds to the Factual Approach Principle.
  - When you purchase items as individuals it is a natural act to inspect what you have purchased before you use it. To neglect to do this may result in you forfeiting your rights to return it later if found defective or nonconforming. When we purchase items on behalf of our employers we may not be as tenacious, so the company has to **enforce its own verification policy as a way of protecting itself from the mistakes of its suppliers.**
  - Another reason for product verification is that it is often the case that characteristics are not accessible for inspection or test after subsequent processing. **Characteristics have not been verified prior to or on receipt may never be verified**. If the end **product passes the prescribed tests** we tend to **assume that the quality of individual components must be acceptable** but there is a risk that it is not and **inherent nonconformities have yet to be revealed**.

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Understanding of Product Audits

- How is this Demonstrated?
- There are several ways of verifying that purchased product meets requirements, but you need to understand that you select the degree of control.
- Assessments by third parties alone would not give sufficient confidence to remove all receiving inspection for deliveries from a particular supplier. You need to examine product as well as the system until you have gained the confidence to reduce inspection and eventually remove it.

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Understanding of Product Audits

- Timing of Verification Activities
- If you have verified that product conforms to the specified requirements before it arrives you can receive product into your company and straight onto the production line. An example of this is where you have performed acceptance tests or witnessed tests on the supplier's premises. You may also have obtained sufficient confidence in your supplier that you can operate a 'just-in-time' arrangement but you must be able to show that you have a continuous monitoring programme that informs you of the supplier's performance.
- If you have not verified that product meets requirements before it arrives you need to install a 'gate through which only conforming items may pass. You need to register the receipt of items and then pass them to an inspection station equipped to determine conformance with your purchasing requirements. If items would normally pass into stores following inspection, as a safeguard you should also make provision for the store person to check that all items received have been through inspection, rejecting any that have not. By use of labels attached to items you can make this a painless routine. If some items are routed directly to the user, you need a means of obtaining written confirmation that the items conform to the prescribed requirements so that at receipt inspection you can provide evidence.

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Understanding of Product Audits

- Evidence to be provided;
  - nothing comes into the company/organisation/site without being passed through inspection;
  - • nothing can come out of inspection into stores without it being verified as conforming
  - If the user is unable to verify that requirements have been met, you will need to provide either evidence that it has passed your receipt inspection or has been certified by the vendor.

Receiving Inspection

- The verification plans should prescribe the acceptance criteria for carrying out receipt inspection. The main aspects to cover are as follows:
- • Define how the receipt inspection personnel obtain current purchasing requirements.
- Categorize all items that you purchase so that you can assign levels of receipt inspection based on given criteria.
- For each level of inspection, define the checks that are to be carried out and the acceptance criteria to be applied.
- Where dimensional and functional checks are necessary, define how the receipt inspection personnel obtain the acceptance criteria and how they are to conduct the inspections and tests.
- • Define the action to be taken when the product, the packaging or the documentation is found to be acceptable.
- • Define the action to be taken when the product, the packaging or the documentation is found to be unacceptable.
- • Define the records to be maintained.

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Understanding of Product Audits

Evaluation of Supplier's Statistical Data

- If the supplier supplies statistical data from the manufacturing process that indicates that quality is being controlled, then an analysis of this data based on assurances you have obtained through site evaluation can provide sufficient confidence in part quality to permit release into the organization. **Where you have required your suppliers to send a certificate of conformity (C of C) testifying the consignment's conformity with the order, you cannot omit all receiving checks. Once supplier capability has been verified, the C of C allows you to reduce the frequency of incoming checks but not to eliminate them**. The C of C may need to be supported with test results therefore you would need to impose this requirement in your purchasing documents. However, take care to specify exactly what test results you require and in what format you require them presented because you could be provided with attribute data® when you really want variables data

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Understanding of Product Audits

Dealing with Product Audits on Supplier's Premises

- Within your procedures you need to provide a means of **identifying which items have been subject to inspection at the supplier's premises** and the receipt inspection action to be taken depending on the level of that inspection. In one case, your representative on the supplier's premises may have accepted the product. In another case, your representative may have accepted a product from the same batch but not the batch that has been delivered. Alternatively, your representative may have only performed a quality audit to gain a level of confidence. **You need to specify the inspection to be carried out in all such cases. Even when someone has performed inspection at the supplier's premises.**
- **The fact that an inspection was carried out is insufficient.** There has to be a statement of what was checked what results have been obtained and a **decision as to whether conformity had been achieved**.
- Without such evidence you may need to repeat some of the inspections carried out on the suppliers premises.

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Understanding of Product Audits

Third Party Assessments or Part Evaluation

- In cases where you don't have the skills or the resources to verify products on suppliers' sites it can be outsourced to a competent organization such as a part evaluation laboratory. This is what is known as Third Party Assessment. You could use the third party to undertake specialist assessments that support your own incoming inspection. This give confidence that the components you receive are built under adequately control conditions

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Understanding of Product Audits

- Legitimizing Verification on Supplier's Premises
- The standard requires that where the organization or its customer intends to perform verification activities at the supplier's premises, the organization is to state the intended verification arrangements and method of product release in the purchasing information,
- What Does this Mean?
- If you choose a verification method other than receipt inspection that involves a visit to the supplier's premises, the supplier has a right to know and the proper vehicle for doing this is through the purchasing information such as a contract or order.
- Why is this Necessary?
- This requirement responds to the Factual Approach Principle.
- The supplier needs to know if you or your customers intend to enter its premises to verify product before shipment so that they may make the necessary arrangements and establish that the proposed methods are acceptable to them.

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Understanding of Product Audits

- How is this Demonstrated?
- Verification by the Organization
- The acceptance methods need to be specified at the tendering stage so that the supplier can make provision in the quotation to support any of your activities on site. When you visit a supplier, you enter its premises only with their permission. The product remains their property until you have paid for it and therefore you need to be very careful how you behave. The contract or order is likely to only give access rights to products and areas related to your order and not to other products or areas. You cannot dictate the methods the supplier should use unless they are specified in the contract. It is the results in which you should be interested not the particular practices unless you have evidence to demonstrate that the steps they are taking will affect the results.

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Understanding of Product Audits

Verification by Your Customer

- In cases where your customer requires access to your suppliers to verify the quality of supplies, you will need to transmit this requirement to your supplier in the purchasing information and obtain agreement. Where a firm's business is relying wholly on that of contracting to customer requirements, a clause giving their customers certain rights will be written into their standard purchasing conditions. If this is an unusual occurrence, you need to identify the need early in the contract and ensure it is passed on to those responsible for preparing subcontracts. You may also wish to impose on your customer a requirement that you are given advanced notice of any such visits so that you may arrange an escort.
- Unless you know your customer's representative very well it is unwise to allow unaccompanied visits to your suppliers. You may for instance have changed, for good reasons, the requirements that were imposed on you as the main contractor when you prepared the subcontract and in ignorance your customer could inadvertently state that these altered requirements are unnecessary.
- When customers visit your suppliers or inspect product on receipt, they have the right to reserve judgement on the final acceptance of the product because it is not under their direct control and they may not be able to carry out all the test and inspections that are required to gain sufficient confidence. **Customer visits are to gain confidence and not to accept product**. The same rules apply to you when you visit your suppliers. **The final decision is the one made on receipt or sometime later when the product is integrated with your equipment and you can test it thoroughly in its operating environment or equivalent**.

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SAPPMA Quality Workshop

	SAPPMA quality Workshop			
	Starting times	Duration	Who	What
9:00	Welcome	5-10	Jan Venter	SAPPMA Introduction to ALS/ Break away groups for discussions
9:15	Introduction to Quality	30-45	Ian Venter	
9:30				
9:45	QA			Testing of Thermoplastics
10:00	Testing of Thermoplastics	60	Reza and Khanya	
10:15	Quality control Testing for the pipe and plastic industry (PVC,HDPE & PP)			
10:30				
10:45	QA			Tea Break announcement
11:00	Tea Break	15		
11:15	Conformance	45	Ian Venter	
11:30				
11:45	Auditing			
12:00	QA			
12:15	SAPPMA Quality going forward	45	Ian Venter	
12:30				
12:45	QA			Lunch announcement /Break away Groups
13:00	Lunch			
13:15				
13:30	Break away groups for discussion	90	Reza & Khanya	SAPPMA
13:45			Room 1	Room 2
14:00			Testing and related	Quality and Related
14:15				
14:30				
14:45				
15:00				

SAPPMA Introduction to Quality

Ian Venter
10-04-2019

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SAPPMA's Purpose

The purpose of SAPPMA is to create absolute customer confidence in the plastic pipe industry and to ensure the long-term sustainability of the industry with top quality piping systems

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Why Quality Control (Standards)

Specific organizations provide standards to the industry who supplies products and services.

End users and specifiers use standards organizations to provide and promote standardized products and services locally and abroad.

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Why Quality Control and where do we need Quality Control (Objective)

Main Objectives

a) to develop, promote and maintain South African National Standards;

b) to promote quality in connection with commodities, products and services; and

c) to render conformity assessment and related services.

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Why Quality Control (Mission)

The Mission is to support national and international systems of innovation and trade

The Ultimate aim is to contribute to uplifting quality of life in all sectors of society

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Elements for Managing System/Product Performance

Concept	ISO Term	Other Term
Output meets requirement	Adequacy	Effectiveness
Results achieved in best way	Suitability	Efficiency
System fulfil the needs	Effectiveness	Adaptability

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Purpose and Objective

- Purpose and objective often interchangeable

- Purpose is often a more permanent state (Reason for Existence)
- Objectives are the transient state and is something aimed for

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Standards

- Standards capture what may be regarded as best practice in a particular field.
- The information in standards has been vetted by those deemed to be experts, (Legitimate authority in the absence of anything more appropriate)
- They are but one of several sources of authoritative information

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A guide to using standards

- Standards are
- a source of information on best practices that can be consulted to identify opportunities
- a set of requirements and recommendations that are implemented
- a criteria for assessing capability of a product, system, or any of its component parts

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Why are standards useful

- Helps form ideas
- Settles arguments
- Clarifies terminology, concepts and principles
- Identify the right things to do
- Identify the conditions for ensuring things are done right

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Before consulting a standard

- Ask Two Questions:
  - **<u>Question 1;</u>**
    - Have you identified and agreed that for some reason you need an improvement in performance
  - **Question 2;**
    - Have you identified and agreed that for some reason you need to be able to demonstrate capability

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Worthy to have in mind prior to consulting a standard

- Understand the intent
- Understand the impact
- Understand how to make it happen
- Understand how to make it a habbit

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Consulting the Standards

- Prior to consulting standards
  - Define the objectives for change
  - Define the strategy for change
- This gives direction
- This gives a means of getting there

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After consulting the Standards

- Put your findings in context.
- Assess the impacts (Benefits and drawbacks).
- Validate the approach with other stakeholders.

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Before we change anything

- Perform a self assessment relevant to the quality aspect and or principle as per organisations key performance indicator.
- Make sure to record a series of benchmarks as this will help with showing progress

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Key Performance indicators that may be of value (Before/After).

- Time to implementation
- Customer satisfaction
- Conformity
- Member perception/Specifier perception
- Cost of processing delays
- External failure costs
- Internal failure costs
- Appraisal costs

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Where do we need quality control

- *System design*
- *Product Design*
- *Standards*
- *Specifications*
- *Manufacturing*
- *Quality management and Control*
- Handling and storage
- *Installation and jointing*
- Pre- commissioning Testing
- Commissioning
- Maintenance and repairs

What gets quality controlled

Manufacturing
Quality management and Control

Bridging the gap

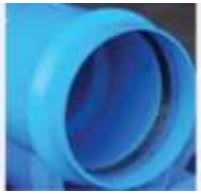
Drilling down into Manufacture Quality

Manufacturer

Division

Department

Product



Component

Raw Materials

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What is Quality control?

Quality control (**QC**) is a process by which entities review the quality of all factors involved in operational matters pertaining production and services.

This approach places an emphasis on three aspects (enshrined in standards such as ISO 9001)

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Three aspects of Quality control

- Elements such as controls, job management, defined and well managed processes, performance and integrity criteria, and identification of records

- Competence, such as knowledge, skills, experience, and qualifications

- Soft elements, such as personnel, integrity, confidence, organizational culture, motivation, team spirit and quality relationships.

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Eight Dimensions of Quality

- Performance
- Features
- Reliability
- Conformance
- Durability
- Serviceability
- Aesthetics
- Perceived Quality

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Dimension of Quality (Performance)

- **Performance**: Performance refers to a product's primary operating characteristics. This dimension of quality involves measurable attributes; brands can usually be ranked objectively on individual aspects of performance.

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Dimension of Quality (Features)

- **Features**: Features are additional characteristics that enhance the appeal of the product or service to the user.

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Dimension of Quality (Reliability)

- **Reliability**: Reliability is the likelihood that a product will not fail within a specific time period. This is a key element for users who need the product to work without fail.

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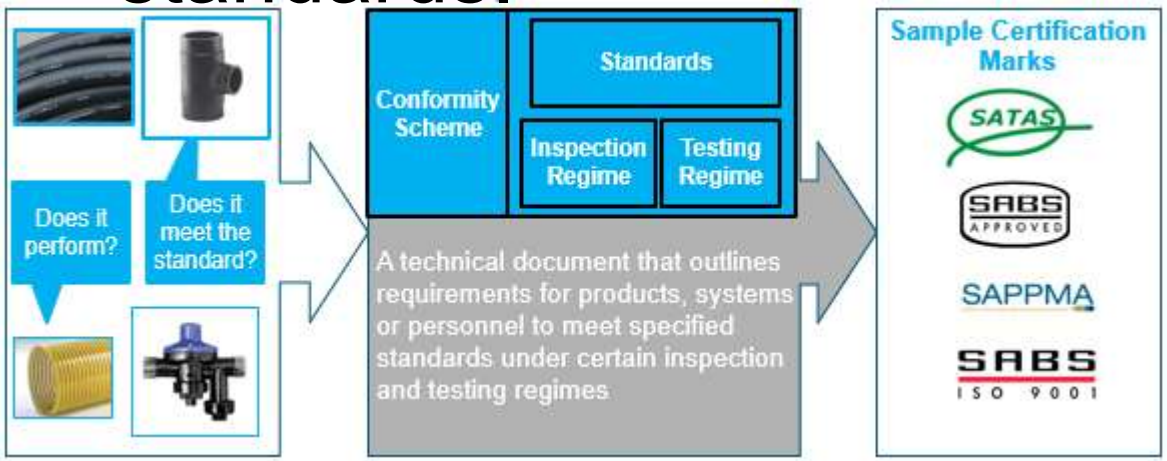
Dimension of Quality (Conformance)

- **Conformance**: Conformance is the precision with which the product or service meets the specified standards.



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Dimension of Quality (Durability)

- **Durability**: Durability measures the length of a product's life. When the product can be repaired, estimating durability is more complicated. The item will be used until it is no longer economical to operate it. This happens when the repair rate and the associated costs increase significantly.

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Dimension of Quality (Serviceability)

- **Serviceability**: Serviceability is the speed with which the product can be put into service when it breaks down, as well as the competence and the behavior of the service person.

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Dimension of Quality (Aesthetics)

- **Aesthetics**: Aesthetics is the subjective dimension indicating the kind of response a user has to a product. It represents the individual's personal preference.

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Dimension of Quality (Perceived quality)

- **Perceived Quality**: Perceived Quality is the quality attributed to a good or service based on indirect measures.

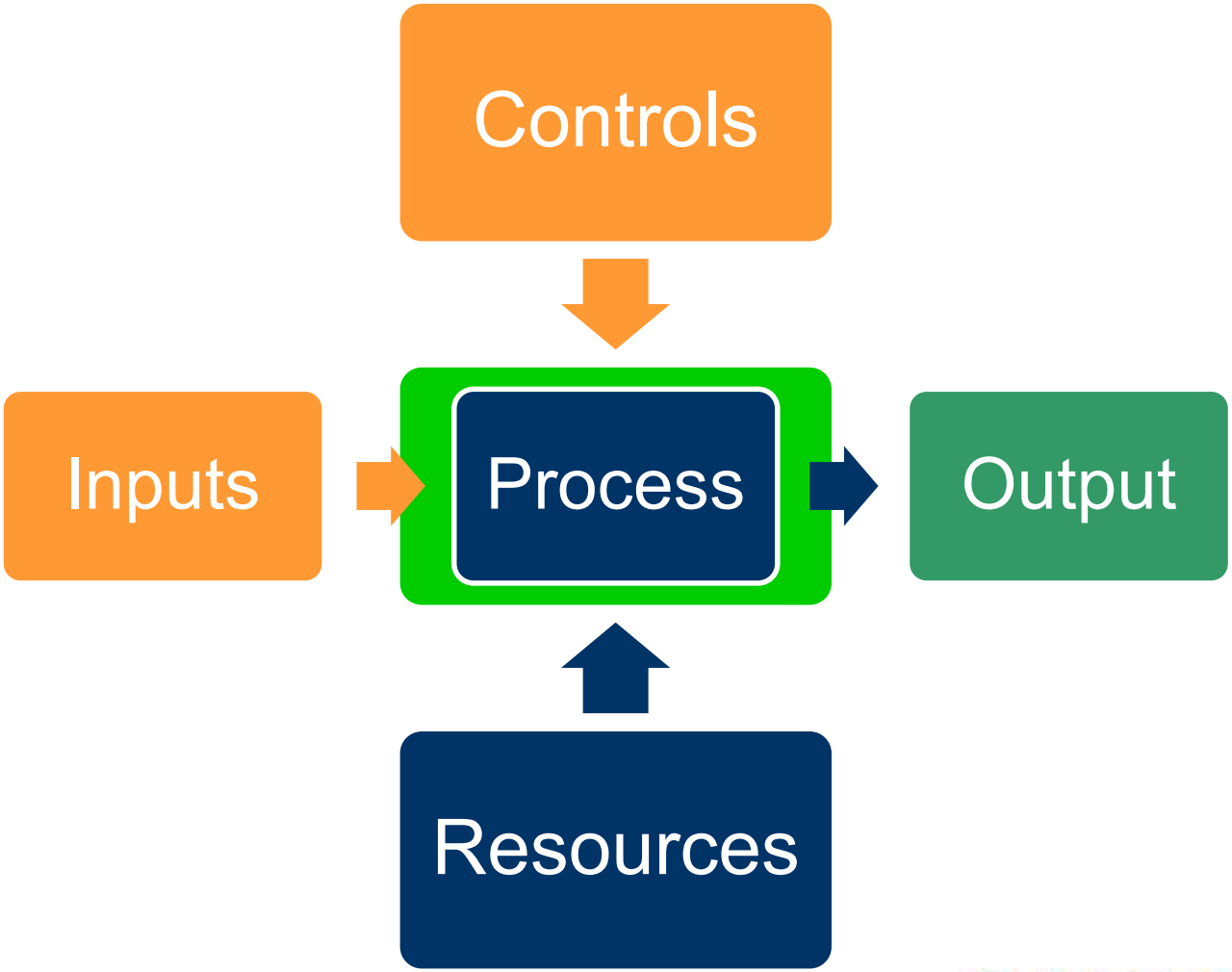
SAPPMA

Simple Process Model

SAPPMA

Unwanted Process Outputs

Updated Process Model



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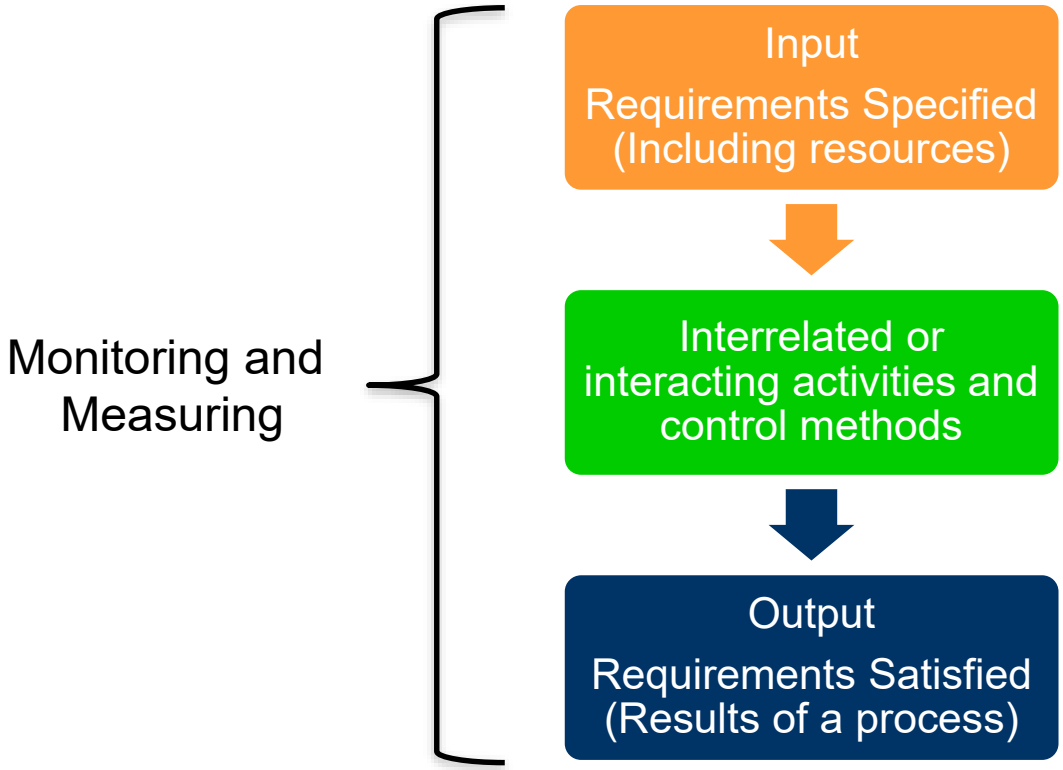
Ideal Process Model



Effectiveness of Process = Ability to achieve the desired result

Efficiency of the of Process = Results achieved vs resources used

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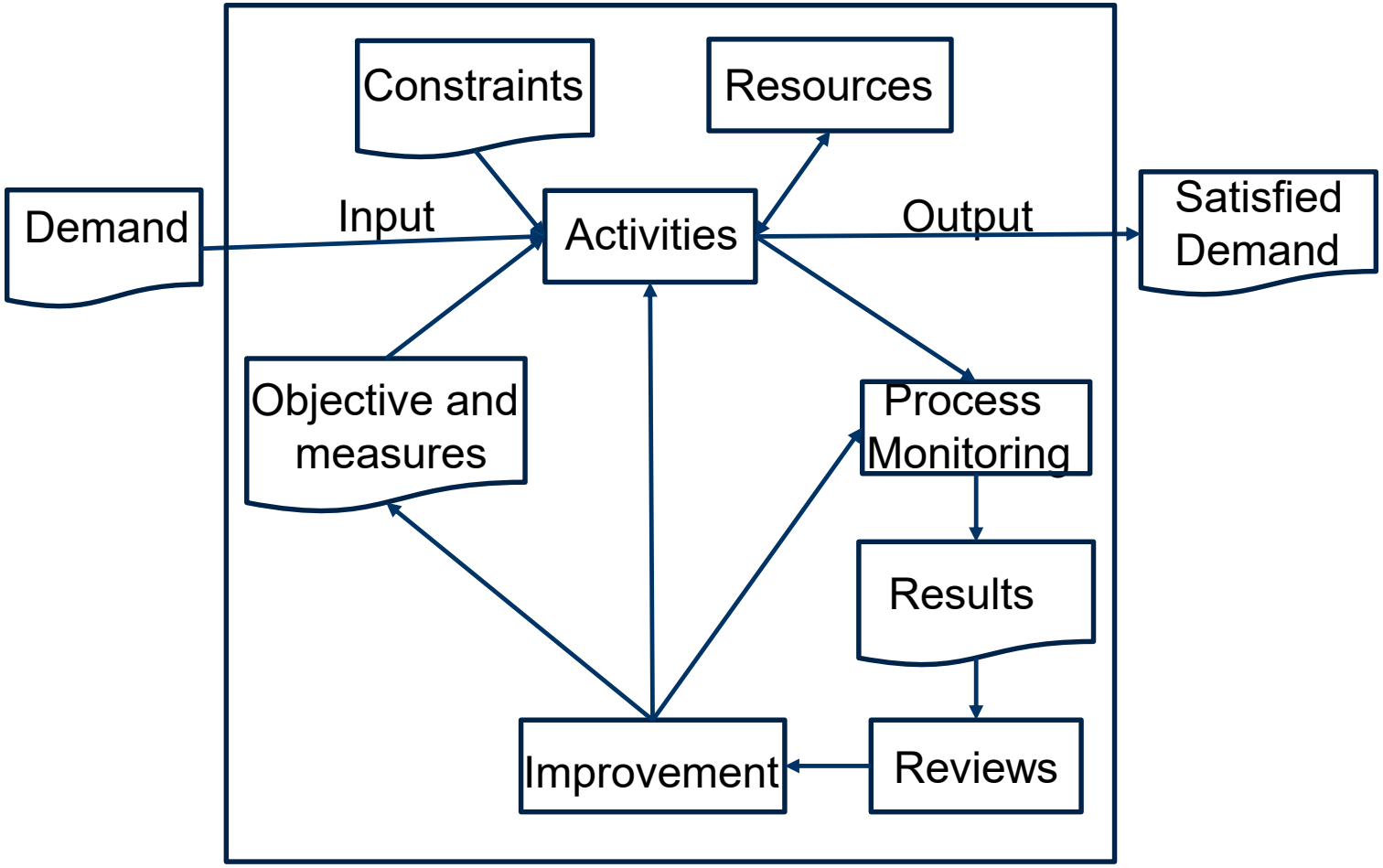
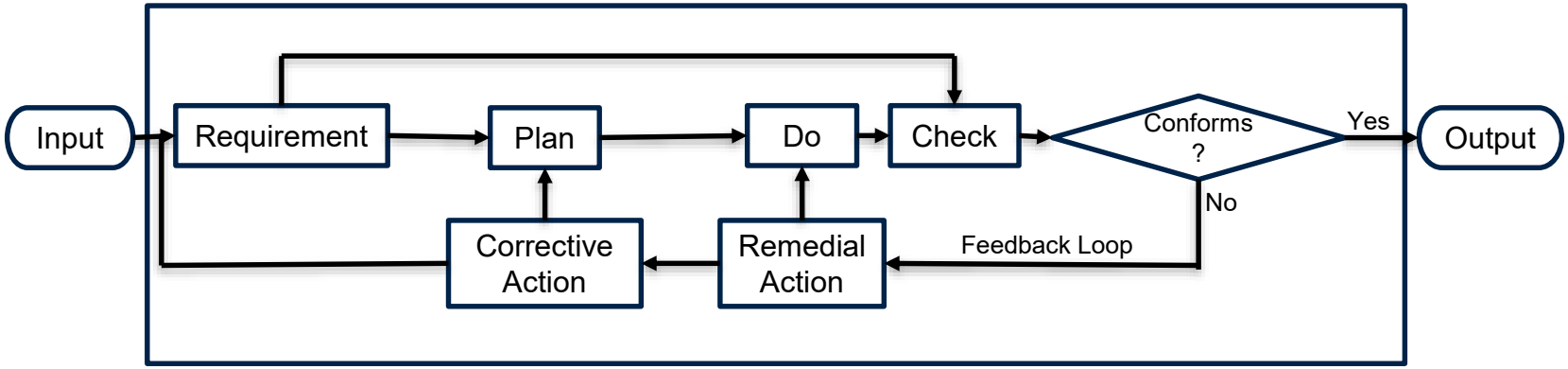
A Managed Process



Generic Control Model



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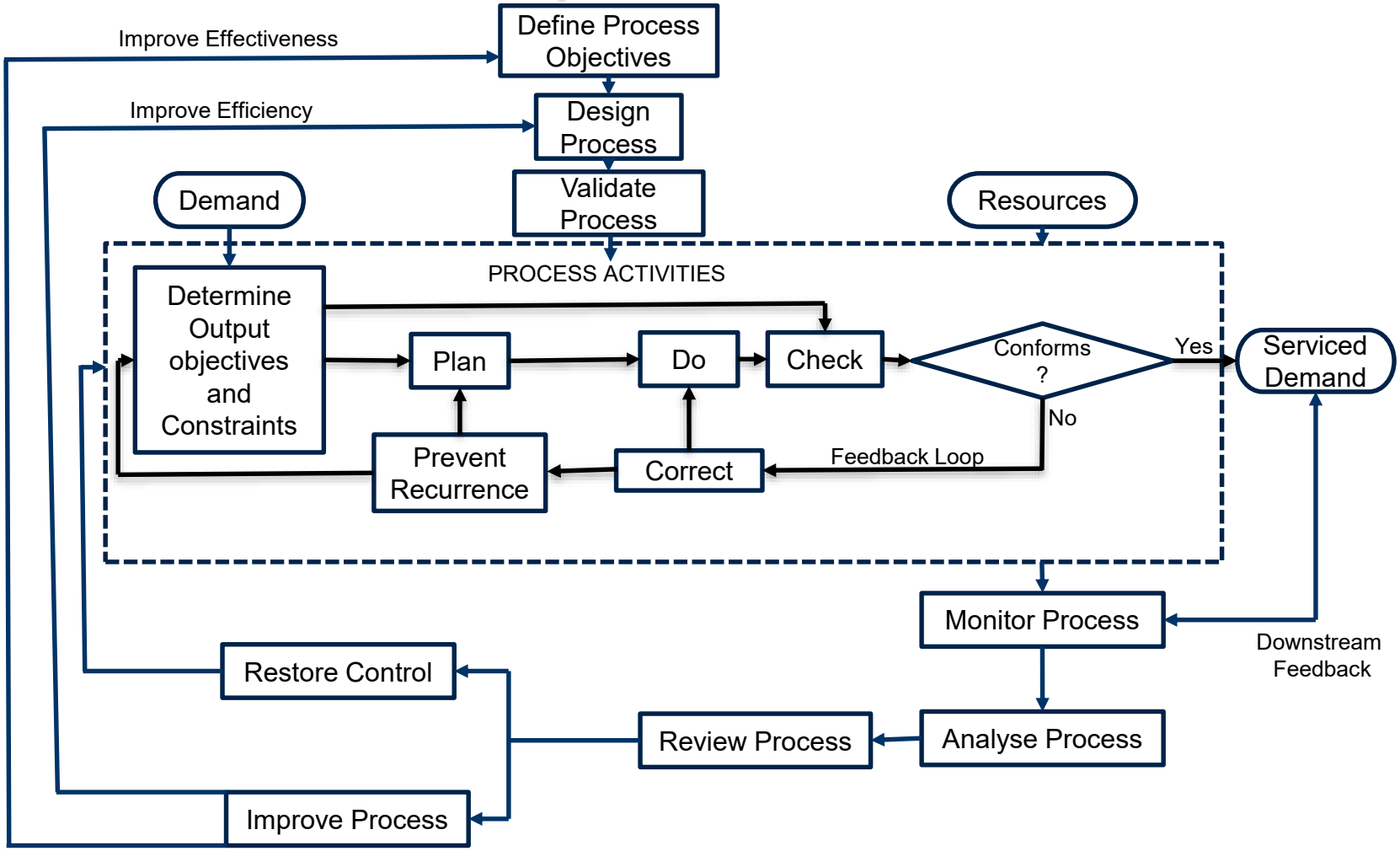
A managed process that is SANS ISO 9001:2008 compatible



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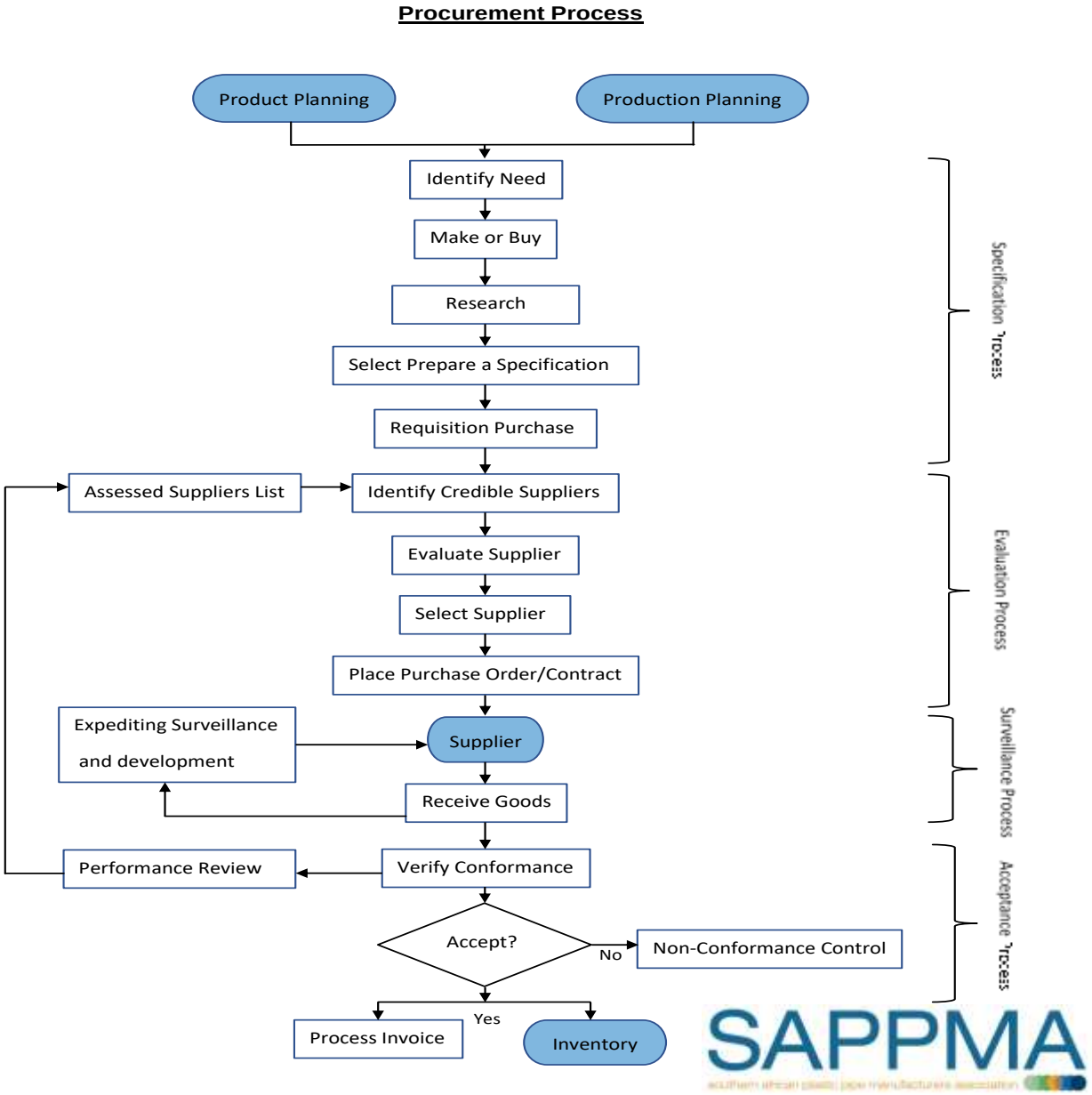
Procurement Process



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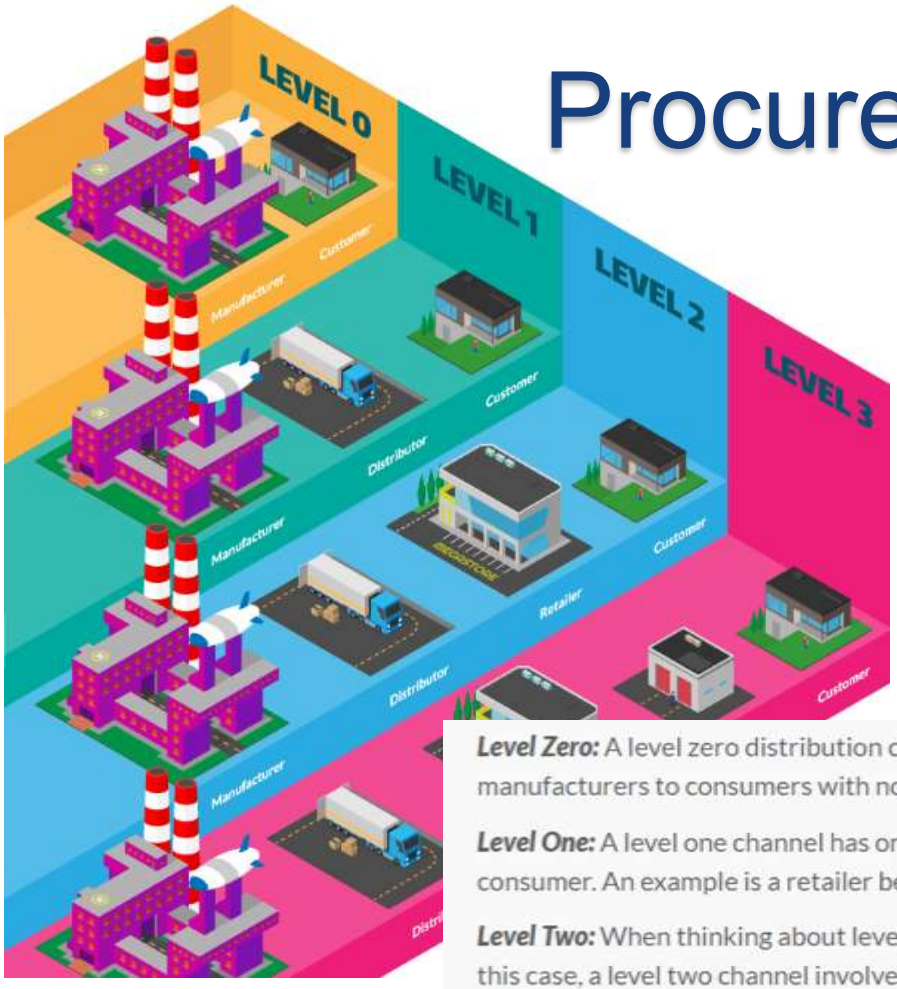
Procurement Process



Level Zero: A level zero distribution channel is the simplest. It involves a direct sale from manufacturers to consumers with no intermediary.

Level One: A level one channel has one intermediary as the middleman between the producer and consumer. An example is a retailer between manufacturer and consumer.

Level Two: When thinking about levels, associate the number to the number of intermediaries. In this case, a level two channel involves two intermediaries between producer and consumer. An example here would be a wholesaler selling to a retailer who then sells to the consumer.

Level Three: Here's where an agent or broker comes in. Agents work on behalf of companies and deal primarily with wholesalers. From here, the wholesalers sell to retailers who then sell to consumers.

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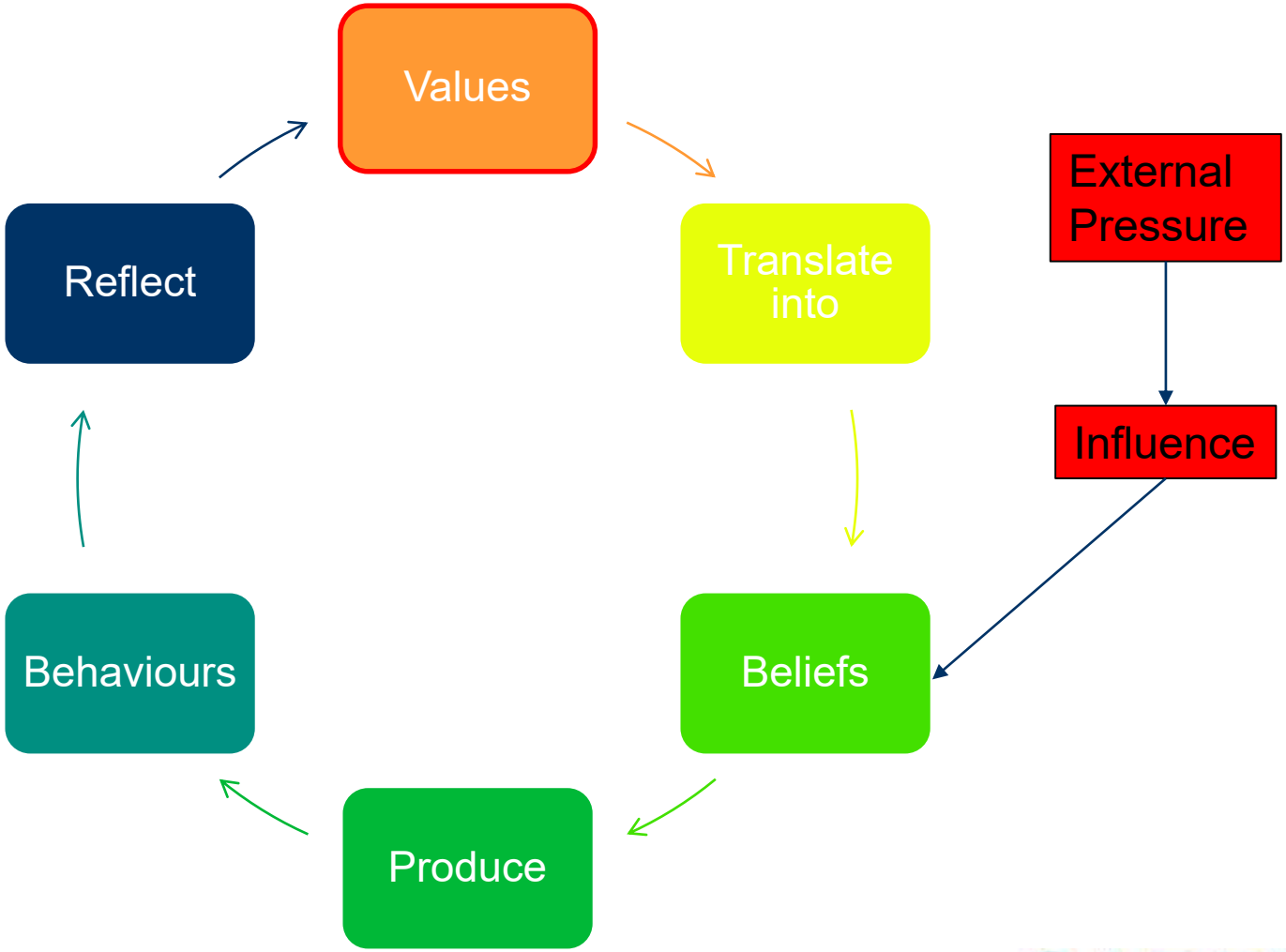
Corporate Terminology we often get wrong

Terminology	Meaning
Purpose	Why we exist, why we do what we do
Mission	A Purpose
Vision	What the organisation should look like as it successfully fulfils its mission
Goals	Strategic Objectives for the long term based on the mission and vision
Values	The beliefs that will guide our behaviour
Strategy	How we are going to get there
Policy	Rules that guide our actions and decisions- the signposts enroute
Principles	Fundamental truth
Objectives	What we want to achieve at key milestones along the journey
Measure	What will indicate achievement
Targets	What we aim at to achieve through the objectives

How come it goes wrong



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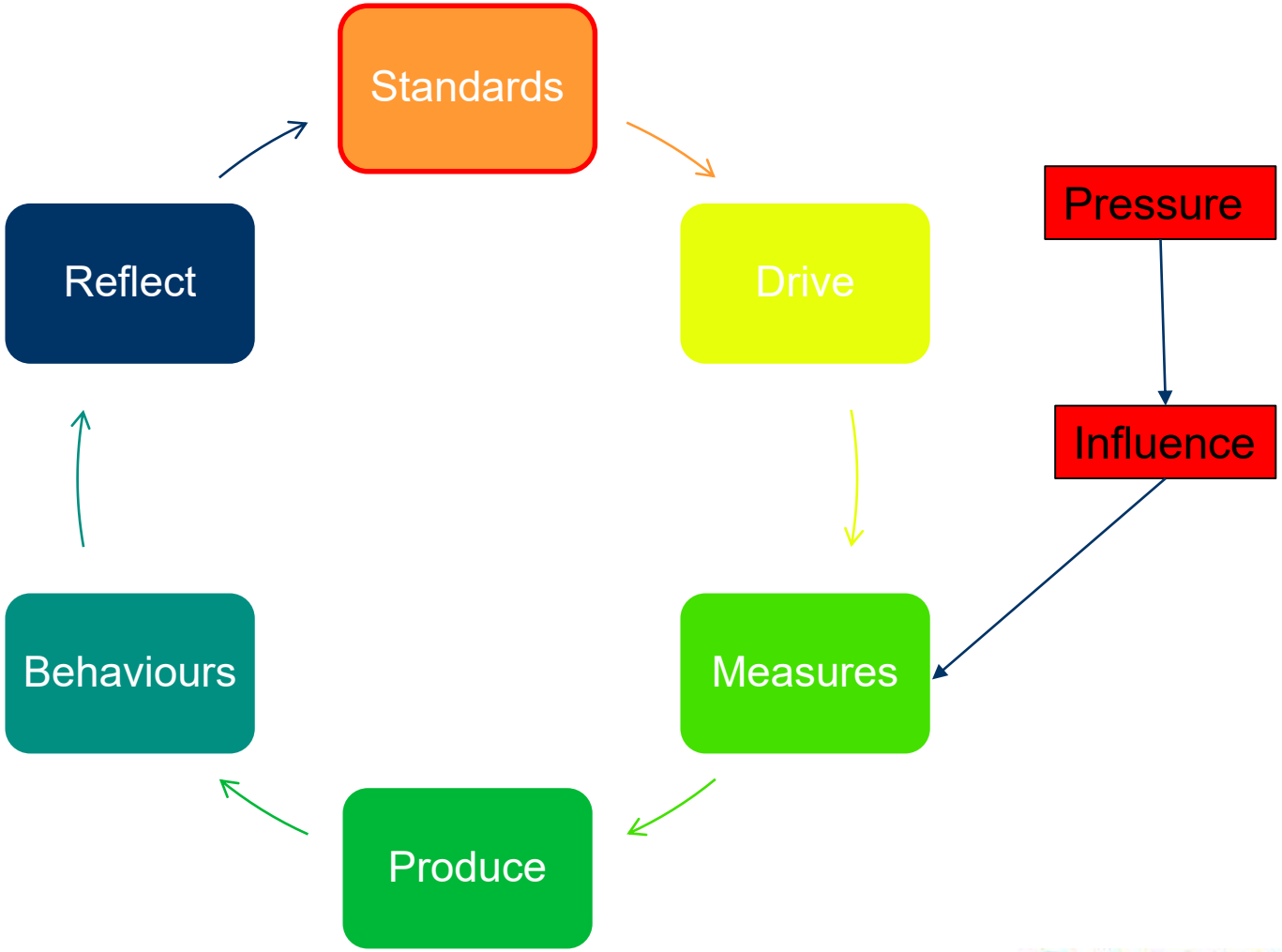
How come it goes wrong



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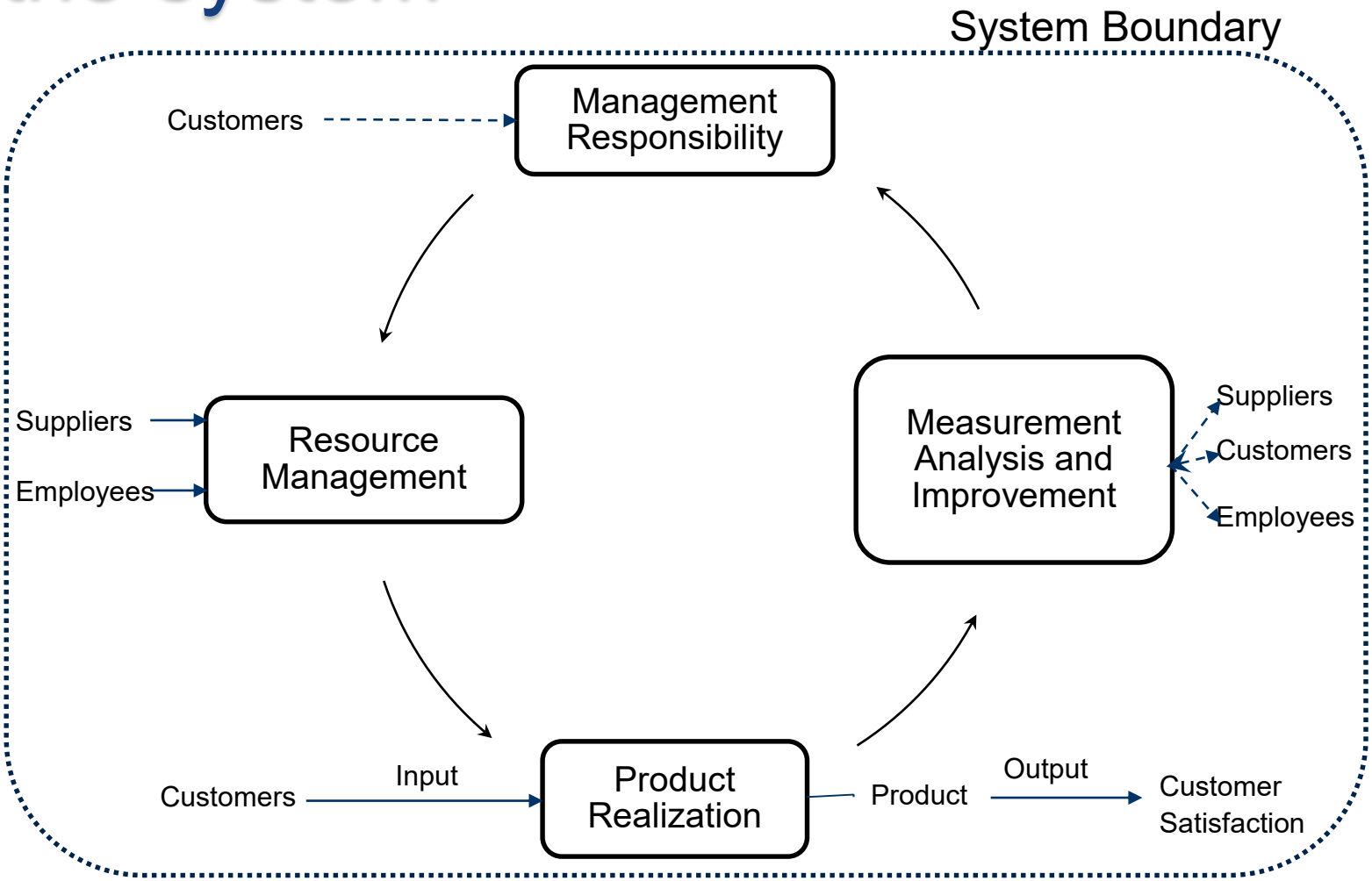
System with Stakeholders inside the system



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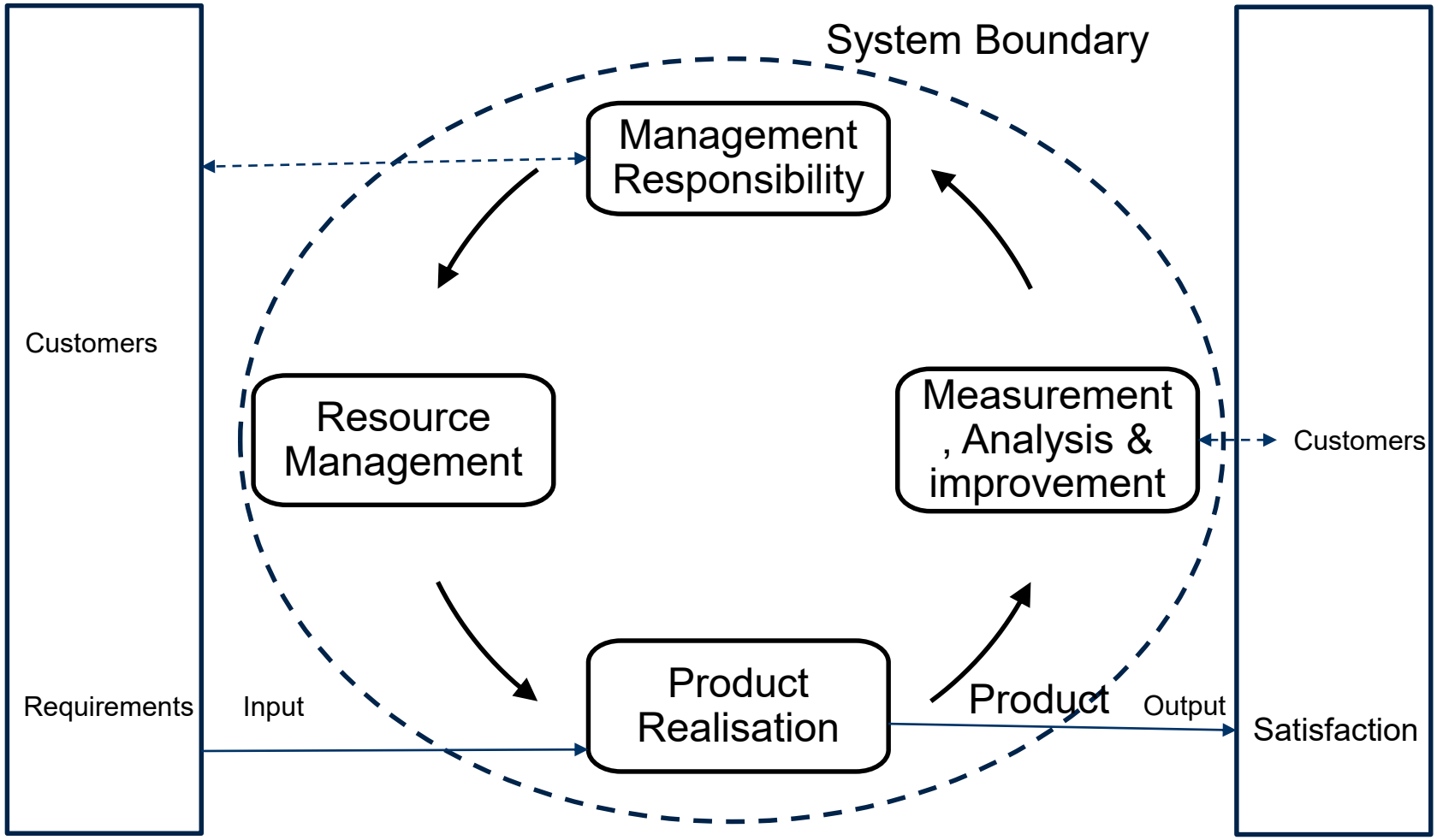
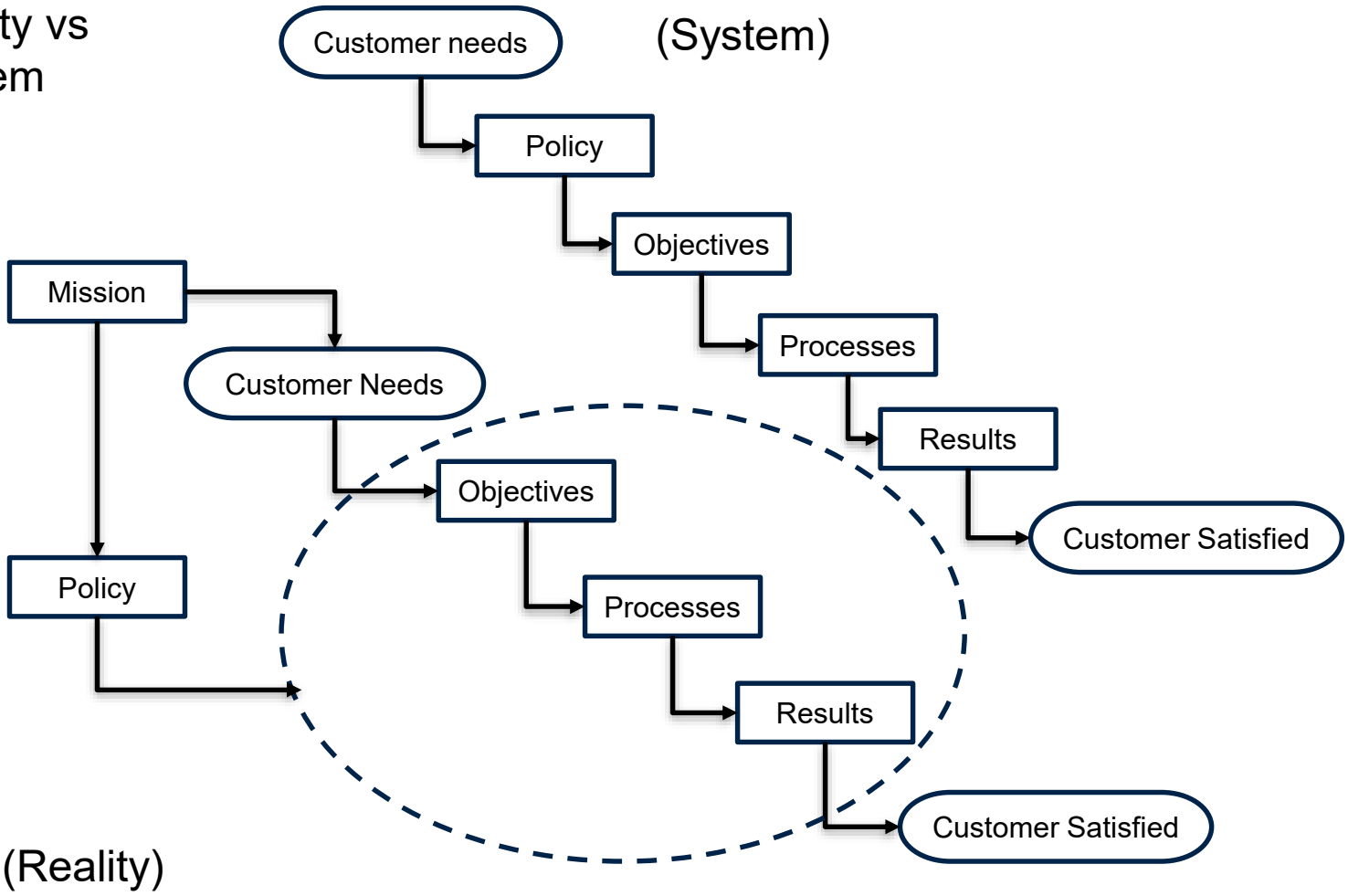
System with Stakeholders outside the system



Policy-Objectives-Process relationship

Reality vs System



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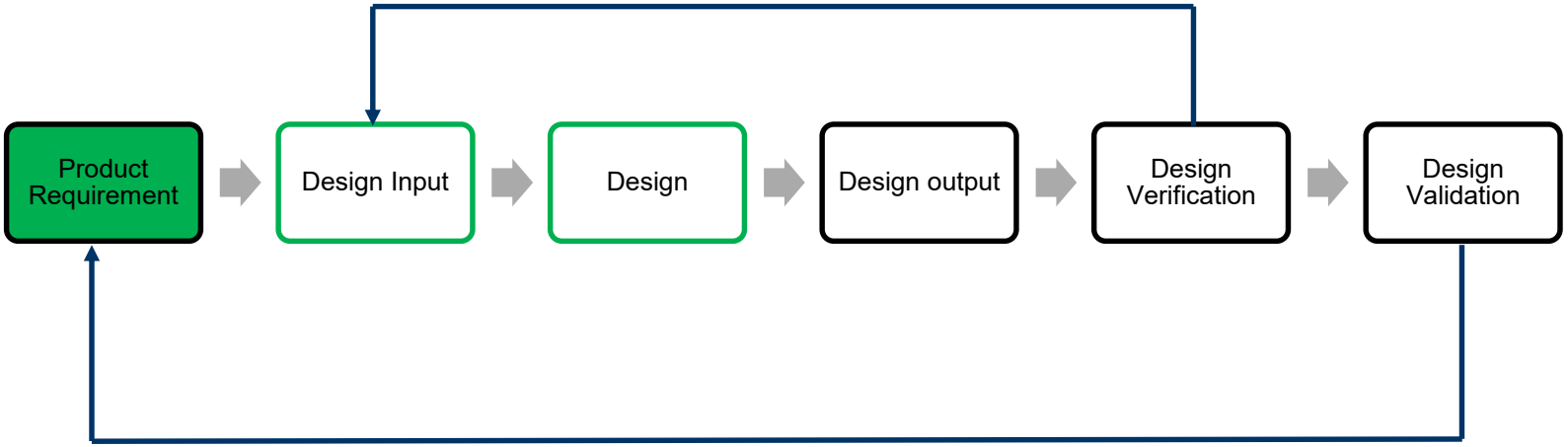
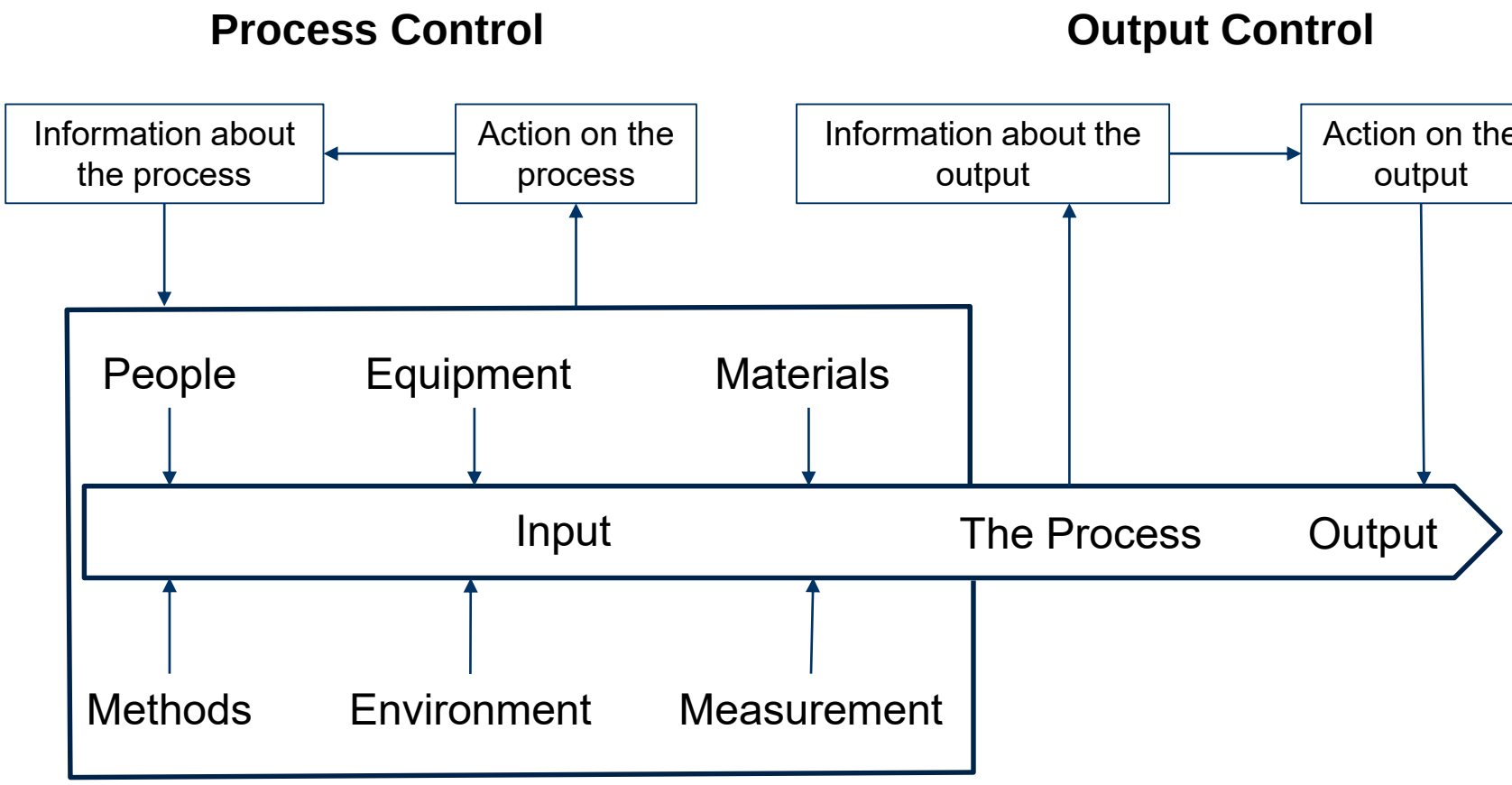
Relationship between design verification and design validation

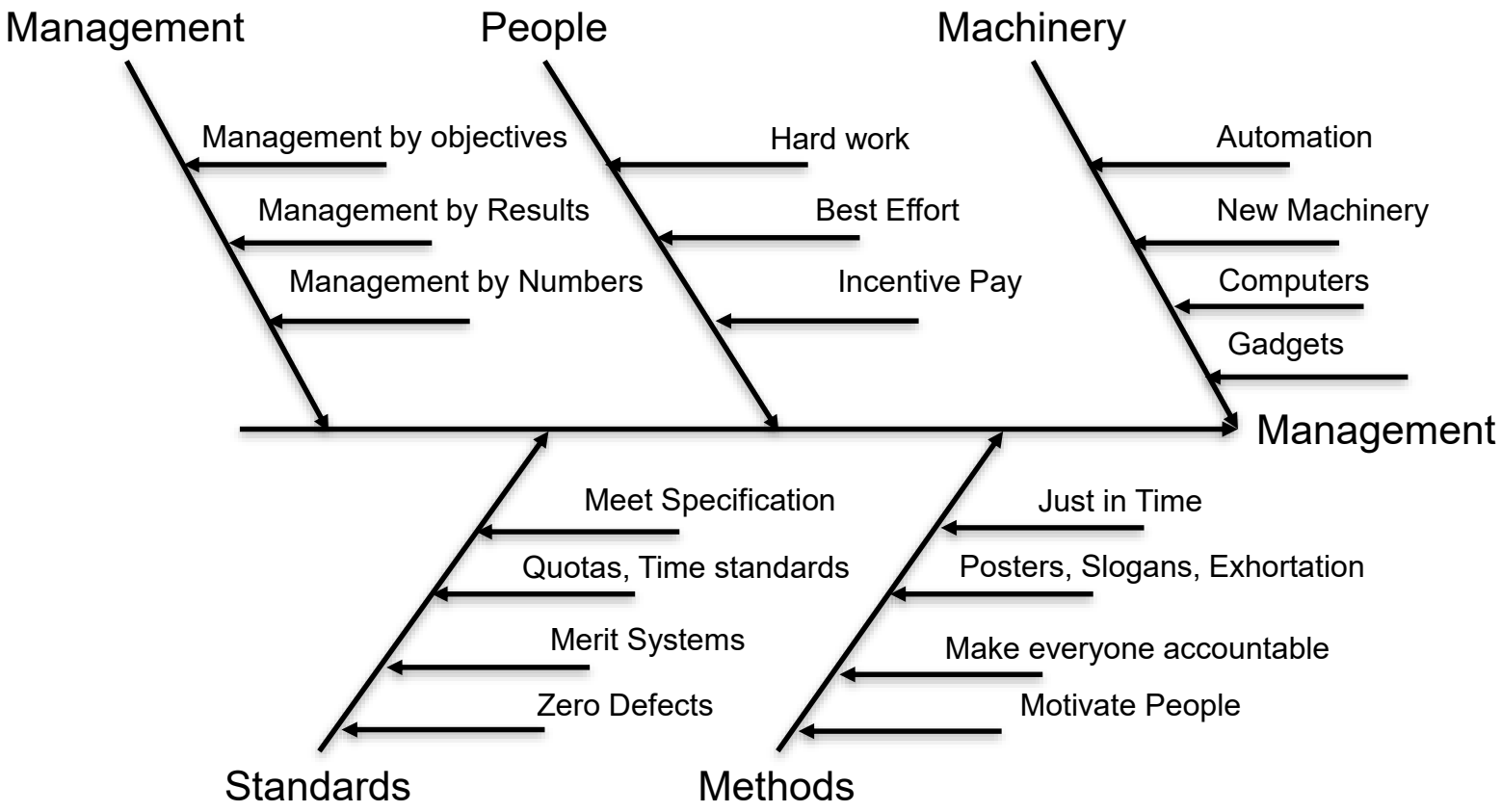
SAPPMA /IFPA influence



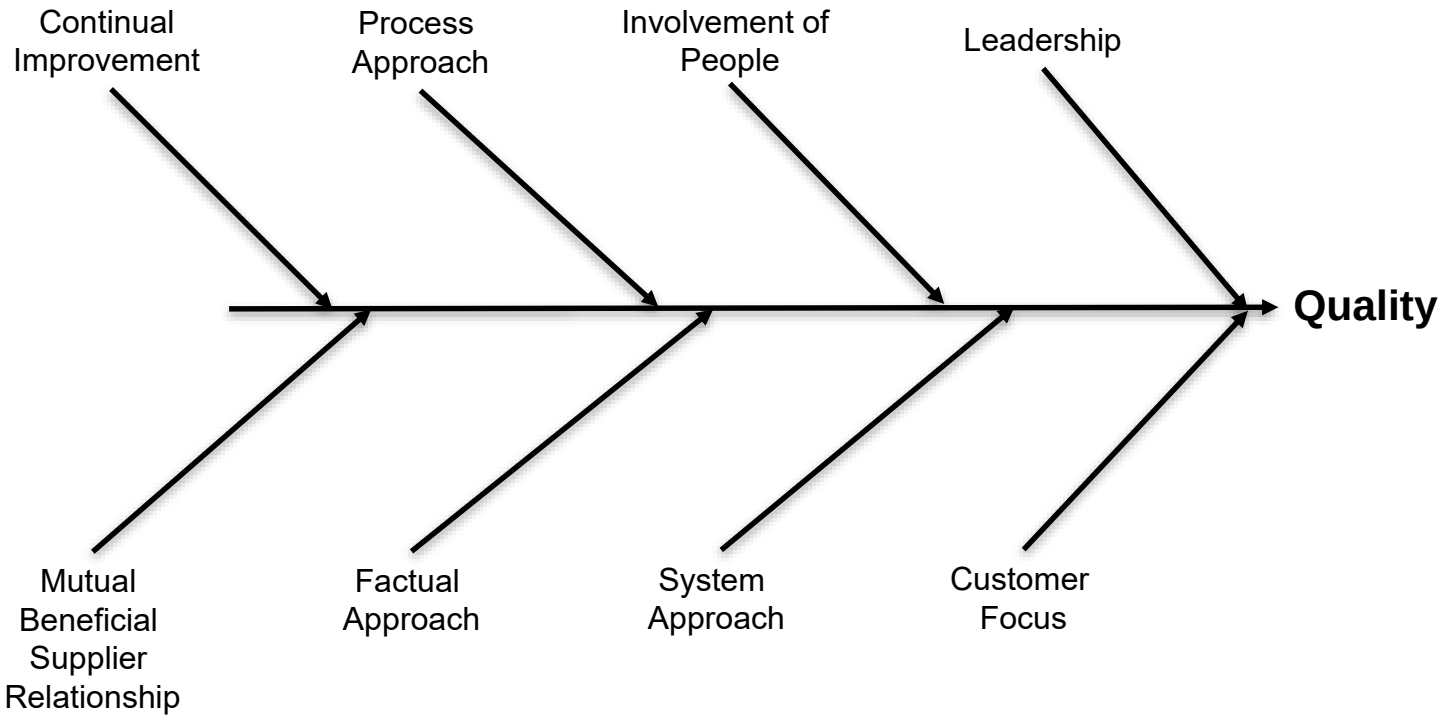
Process Control Model



Inappropriate determinants of Quality



The 8 Quality management Principles



What Policies do we have

Policies related to	Example of wording
Customers/Members	We will listen to our customers/members, understand their needs and expectations and endeavour to satisfy those needs and expectations in a way that meets the expectations of our other stakeholders
Environment, Health and Safety	We will operate in a manner that safeguards the environment and the health and safety of those who could be affected by our operations
Leadership	We will establish and communicate our vision for the organisation and through our leadership exemplify core values and guide the behaviour of all to achieve our vision
People	We will involve our people in the organisations development, utilize their knowledge and experience, recognize their contribution and provide an environment in which they are motivated to realize their full potential
Process and Systems	We will take a process approach towards the management of work and manage our processes as a single system of interacting processes that produce outcomes which satisfy all our stakeholders
Continual improvement	We will provide an environment in which every person is motivated to continually improve the efficiency and effectiveness of our products, processes and our management system.
Decisions	We will base our decisions on the logical and intuitive analysis of data collected where possible from accurate measurement of product, process and system characteristics
Supplier Relationships	We will develop alliances with our suppliers and work with them to jointly improve performance
Profits	We will satisfy our stakeholders in a manner that will yield a surplus that we will use to develop our capabilities and our employees, reward our investors and contribute to the improvement in our society

Policy to Objectives

Policy

We are committed to providing products that are delivered on time and meet customer requirements while yielding a profit and increasing sales. We accomplish this through product and process innovation, cost reduction activities and compliance with QMS requirements

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Quality Objectives from Quality Policy

Quality Policy	Quality Objectives
We are committed to providing products that are delivered on time	98% on time delivery as measured by the customer
and meet customer requirements	99% of the monthly output to be defect free as measured by customer returns
while yielding a profit	5% profit on annual sales
and increasing sales	25% increase in annual sales
We accomplish this through product and process innovation	20% of our product range will contain new products and 50 improvement teams will be set up to seek process improvements
cost reduction activities	15% reduction in cost of poor quality as a percentage of sales
and compliance with QMS requirements	Certified processes audited by independent third party inspectors

After all agree on the Policy

- Ensure the policy is presented in a user friendly way
- Announce to all roll players that we have a policy that affect everyone
- Publish the policy internally as well as externally
- Display the policy in key places to attract peoples attention
- Arrange and implement training or instruction for those affected
- Test understanding at every opportunity E.g. at meetings, when issuing instructions or procedures, when delays occur, when failures arise and when costs escalate.
- Audit the decisions taken that affect the quality and go back to those who made them if they do not comply to the policy.
- Take action every time there is misunderstanding. Do not let it go unattended and do not admonish those who may have misunderstood the policy. It may not be their fault
- Every time there is a change in policy, go through the same process. Never announce a change and walk away from it. The change may never be implemented.
- Give time for the understanding to be absorbed. Use case studies and current problems to get the message across

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Policy and the Audit Programme

- Do not only ask what is the quality policy
- How does the quality policy affect what you do?
- What happens if you can not accomplish or adhere to the policy
- What will you do if you discovered non-conformances
- How will you treat a customer who continuously complain about your products and services
- What action will you take if someone asked you to undertake a task for which you were not trained for
- What are your objectives and how do they relate to the quality policy
- What action will you take if you find a person acting outside the policy

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How did it change?

From Conformity

Customer Satisfaction

Sustained Success

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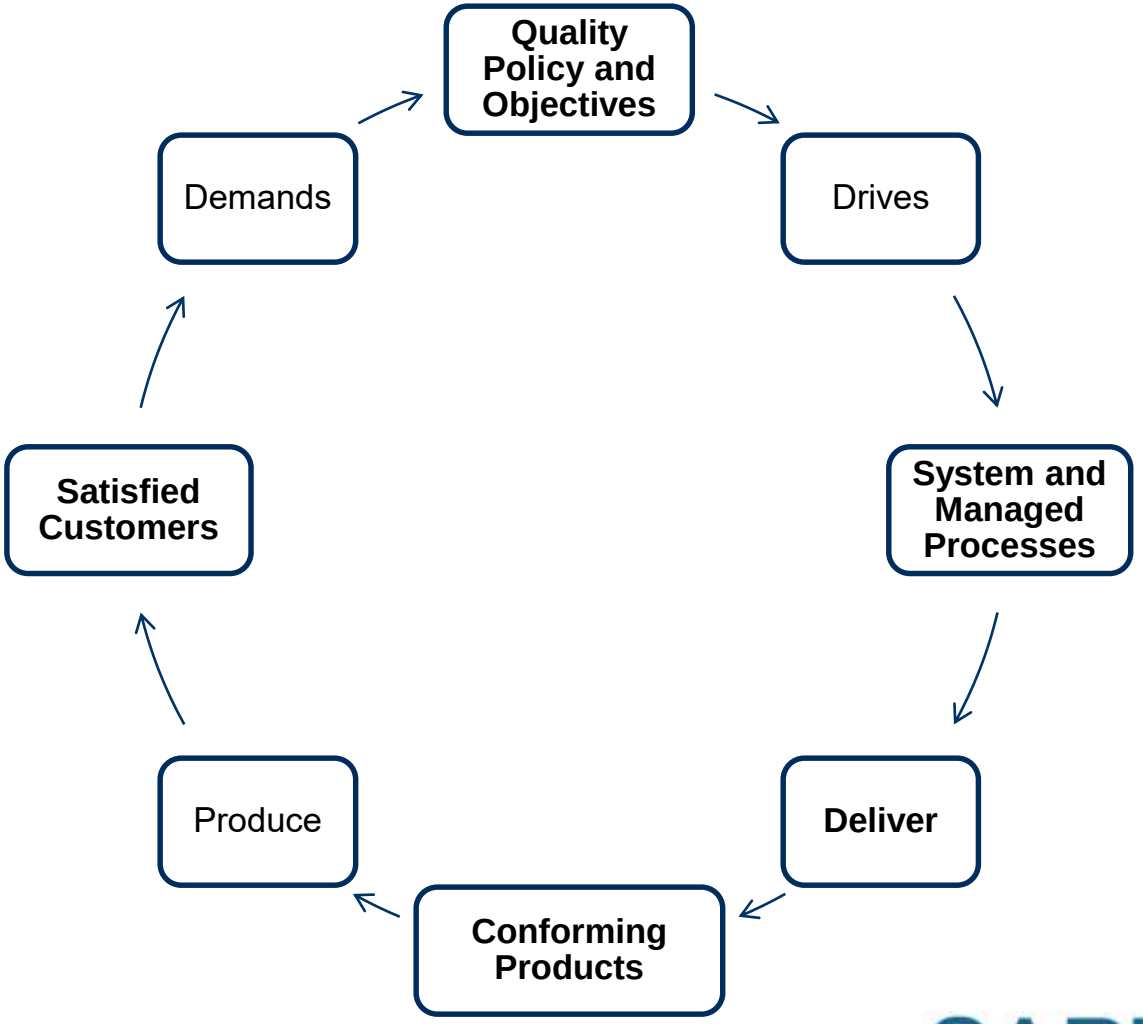
Conformity


Quality Policy and Objectives
Generates
Documented Procedures
Provides
Quality Records
Demonstrates
Conformity
Drives

Customer Satisfaction



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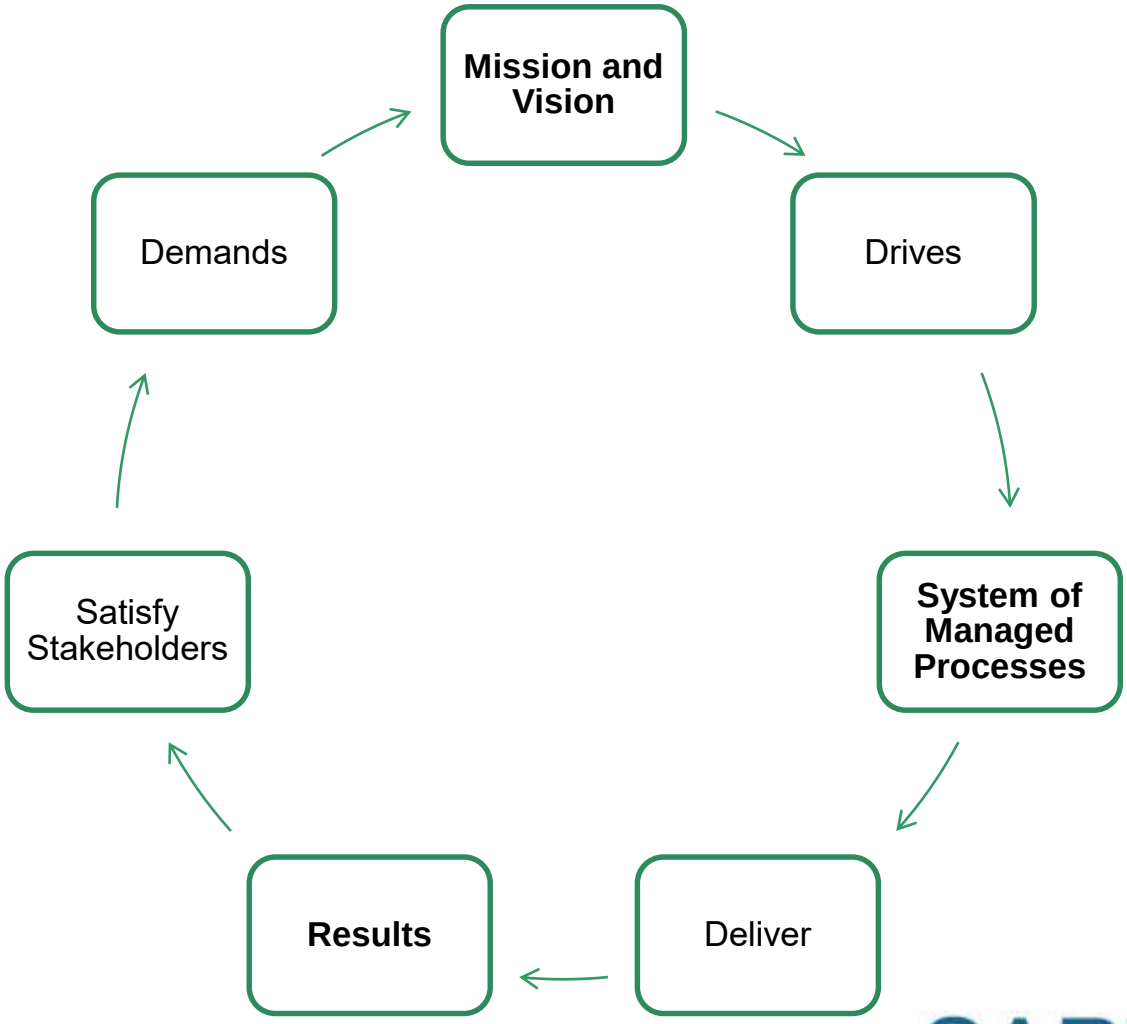
Sustained Success



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Principles Representing Factors for achievement of Quality

1. Understanding customer needs and expectations
2. Creating a unity of purpose and a quality culture
3. Developing and motivating the people
4. Managing processes effectively
5. Understanding interactions and interdependencies
6. Continuously seeking better ways of doing things
7. Basing decisions on facts
8. Realizing that you need others to succeed

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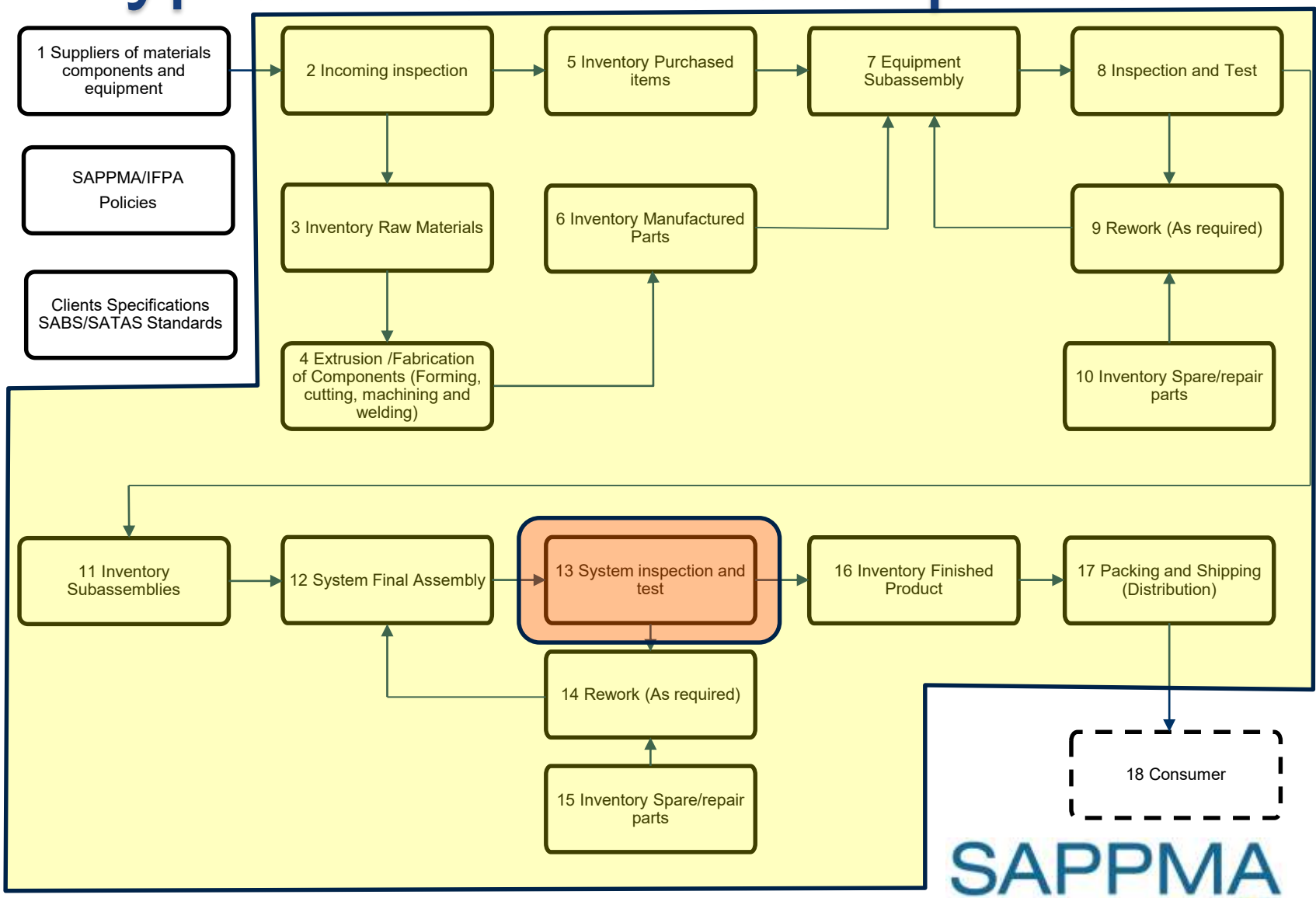
Typical Manufacturer process



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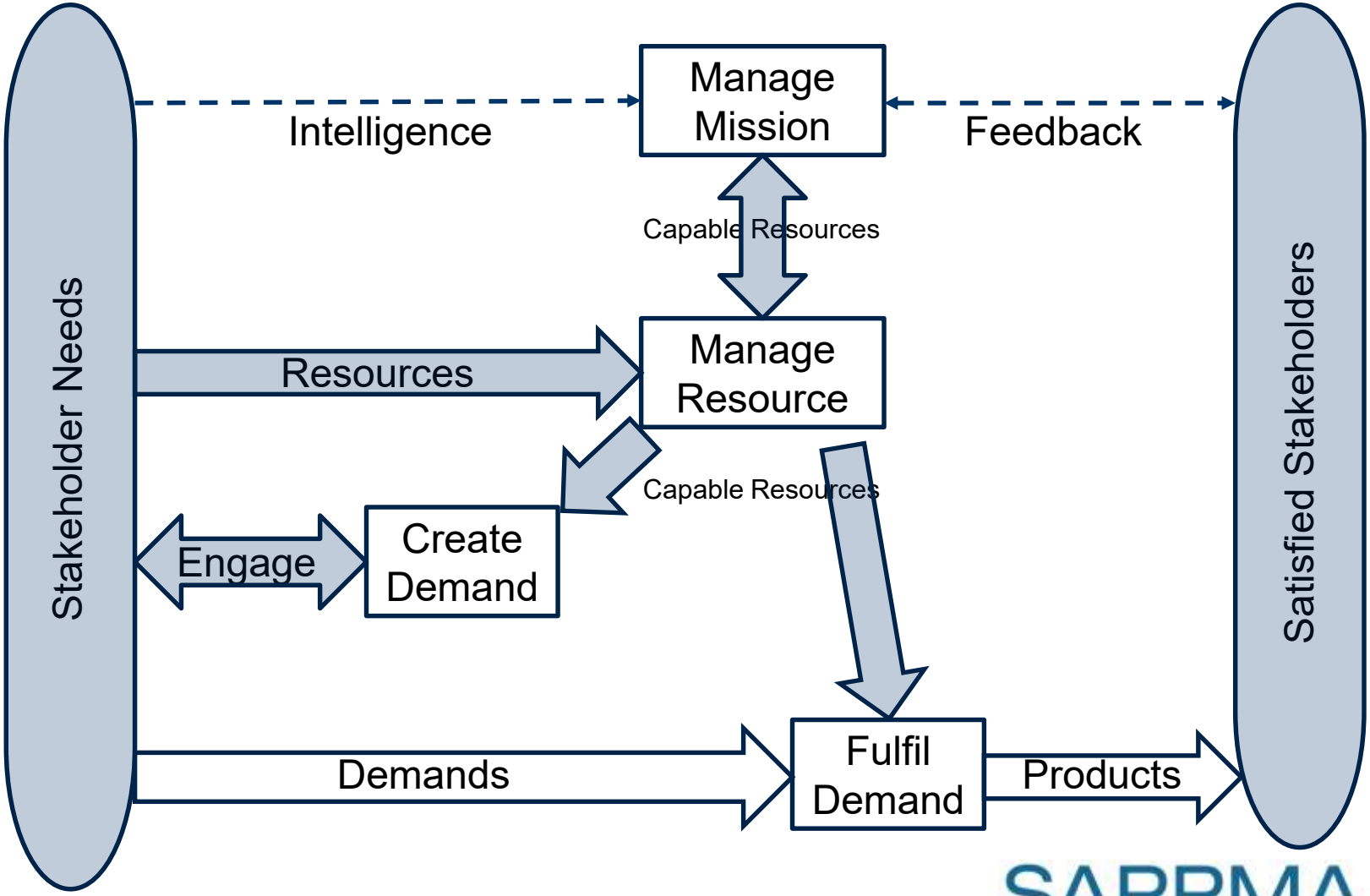
The Generic System Model



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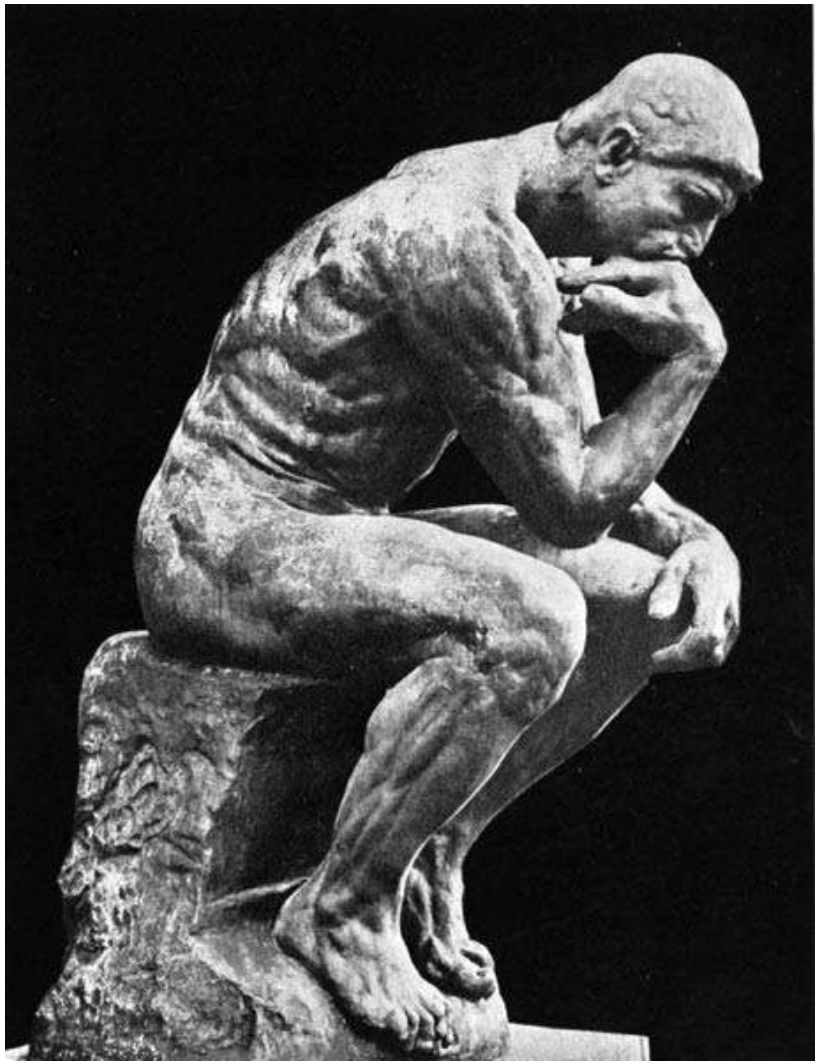
Questions and Answers



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Quality Control testing for the Pipe and Plastics Industry

Reza Theunissen (Instron)

Khanya Ngobo (TA Instruments)

Advanced Laboratory Solutions

Overview

- Mechanical Testing
- Microscopy and Measurement
- Thermal Analysis
- Bulk Density

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Section Structure

- Principle
- Importance
- Equipment required
- Relevant testing standards
- Important notes

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Mechanical Testing

- Tensile
- Compression
- Bend/ Flexure
- Impact
- Melt Flow Index
- HDT/ VST

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Tensile Testing

- Principle:
  - Uniaxial deformation
  - Elongation
  - Tensile Strength
- Importance:
  - Strength of material to resist outward pull/ tension
- Equipment required:
  - Universal testing machine
  - Suitable grips
  - Reporting software
  - Strain measurement devices

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Tensile Testing

- Relevant Standards:
  - ISO 527
  - ASTM D638
  - ASTM D3915 (PVC)

- Important Notes:
  - Adherence to standards
  - Sample preparation
  - Whole pipe vs segment
  - Specimen alignment
  - Strain Measurement
  - Balancing load
  - Calibration
  - Maintenance
  - Method development
  - Reporting

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Compression Testing

- Principle:
  - Uniaxial Deformation
  - Deformation
  - Compressive Strength
- Importance:
  - Strength of material to resist inward push/ compression
- Equipment required:
  - Universal testing machine
  - Suitable compression platens
  - Reporting software
  - Strain measurement devices (LVDT)

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Compression Testing

- Relevant Standards:
  - ISO 844
  - ASTM D695
  - ASTM D2412 (Pipe)

- Important Notes:
  - Adherence to standards
  - Sample preparation
  - Whole pipe vs segment
  - Specimen alignment
  - Strain Measurement
  - Crush resistance test
  - Calibration
  - Maintenance
  - Method development
  - Reporting

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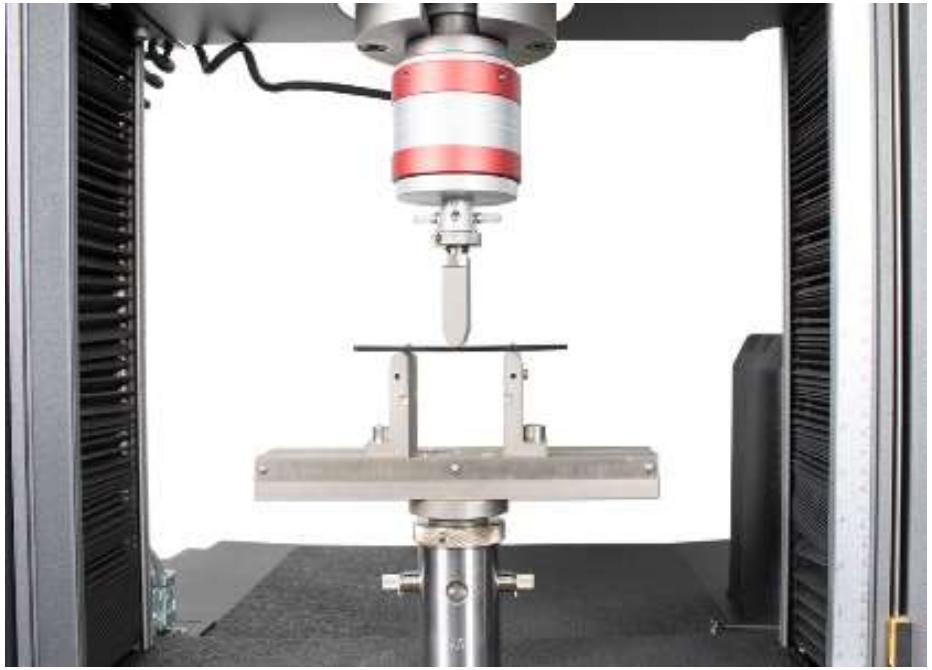
Bend/ Flexural Testing

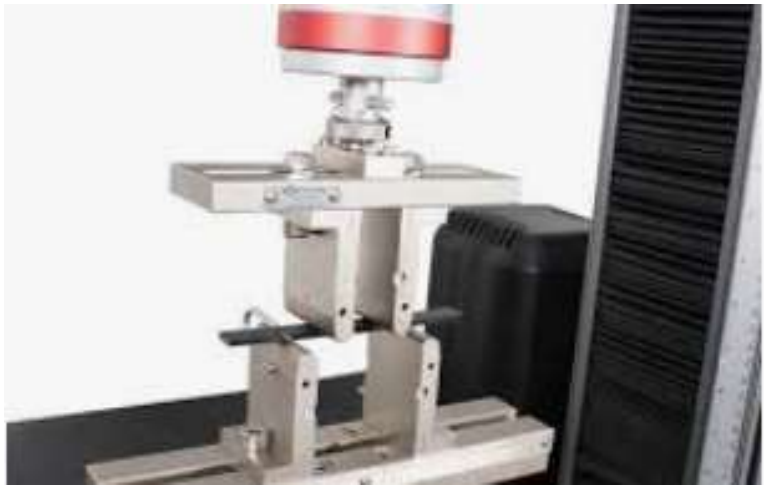
- Principle:
  - Uniaxial deformation
  - Compressive deflection
  - Flexural modulus
- Importance:
  - Stiffness of material to resist bending/ deformation
- Equipment required:
  - Universal testing machine
  - 3/ 4 point bend fixture
  - Reporting software
  - Strain measurement devices



Bend/ Flexural Testing

- Relevant Standards:
  - ISO 178
  - ASTM D790

- Important Notes:
  - Adherence to standards
  - Sample preparation
  - Whole pipe vs segment
  - Specimen alignment
  - Strain Measurement
  - Flexural modulus
  - Calibration
  - Maintenance
  - Method development
  - Reporting



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Impact Testing

- Principle:
  - Energy absorbed during fracture
  - Ductile vs brittle material
  - Toughness measurement
- Importance:
  - Toughness of material to absorb energy during plastic deformation
- Equipment required:
  - Droptower/ Pendulum impact tester
  - Appropriate hammer
  - Appropriate anvils and shoulders
  - Software optional

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Impact Testing

- Relevant Standards:
  - ISO 179, 180
  - ASTM D2444, D6110

- Important Notes:
  - Adherence to standards
  - Sample preparation
  - Charpy vs Izod
  - Gardner Impact
  - Uninstrumented testing
  - Instrumented testing
  - Calibration/ Verification
  - Maintenance
  - Reporting

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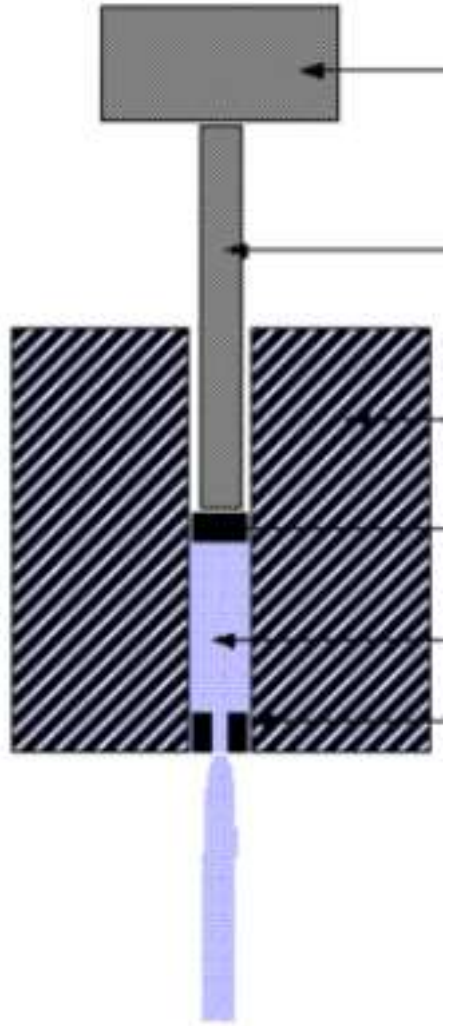
Melt Flow Index Testing

- Principle:
  - Ease of flow of the melt of a thermoplastic polymer
  - Processability of material
  - Temperature; weight; set die diameter
- Importance:
  - Performance of polymer in plant extruder
- Equipment required:
  - Melt flow tester with weights
  - Encoder/ analytical balance
  - Cutting and Timing devices
  - Cleaning equipment



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Melt Flow Index Testing

- Relevant Standards:
  - ISO 1133
  - ASTM D1238

- Important Notes:
  - Adherence to standards
  - PVC/ Corrosive material
  - Temperature
  - Weight
  - Automation
  - High flow materials
  - Maintenance
  - Reporting

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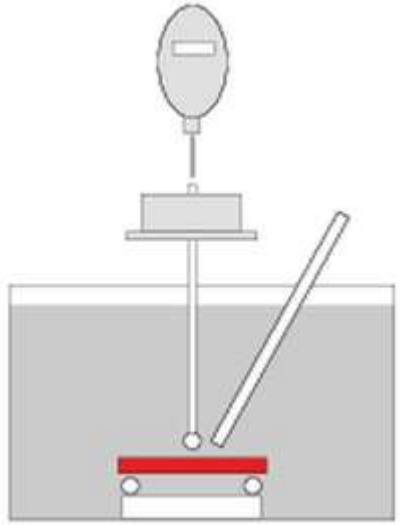
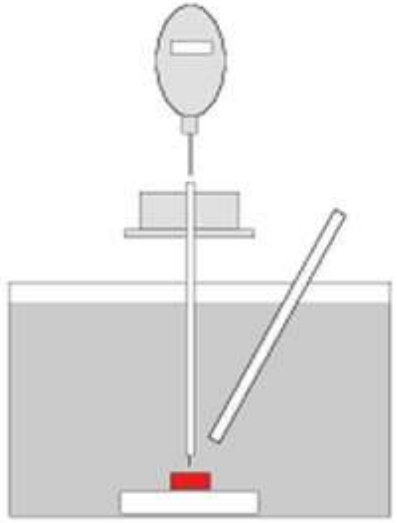
HDT/ VST Testing

- Principle:
  - Heat Deflection Temperature
  - Vicat Softening Temperature
  - Oil bath heated, temperature recorded at a specific deflection (HDT) or indentation (VST)
  - Load and heating rate
- Importance:
  - Temperature resistance of plastics for different applications
- Equipment required:
  - HDT or VST system
  - Oil bath
  - Weights
  - Reporting system/ software





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HDT/ VST Testing

- Relevant Standards:
  - Vicat: ISO 306 and ASTM D1525
  - HDT: ISO 75 and ASTM D 648

- Important Notes:
  - Adherence to standards
  - Temperature rate
  - Weights applied
  - Automation
  - Multi-station
  - Maintenance
  - Reporting

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Sample Preparation

- Tensile
- Bend/ Flexure
- Impact
- HDT/ Vicat

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Microscopy and Measurement

- Atomic Force Microscopy
  - Morphology of extruded pipe
- Stereo Microscopy
  - Measurement and surface structure
  - Carbon black dispersion
- Magna Mike Ultrasound
  - Pipe wall thickness
- Hydrostatic Pressure Testing

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Thermal Analysis

- Oxidative Inductive Time
- Melting and Crystallization
- Humidity Ageing
- Water Adsorption
- Environmental Stress Cracking Resistance

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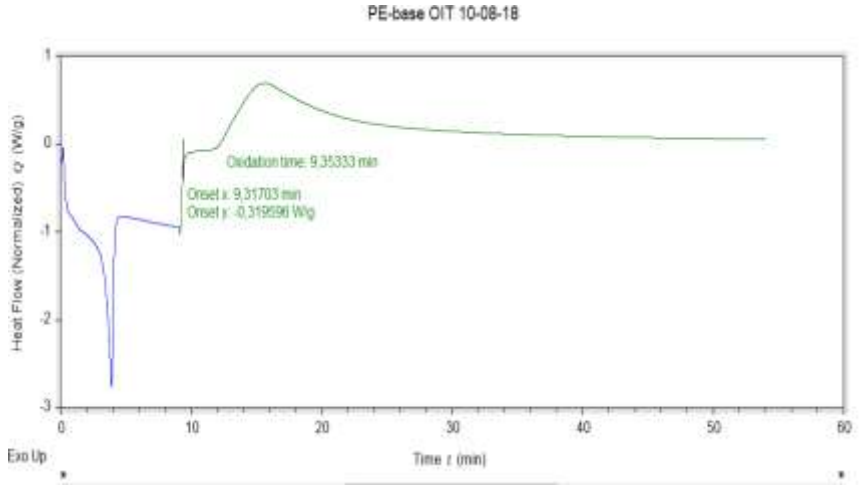
Oxidative Inductive Time

- Principle:
  - Process conditions and time for material
- Importance:
  - Retention time of a material as a polymer melt while processing prior to degradation
- Equipment required:
  - TGA/DSC/SDT
  - Sample pans/cups
  - Purge gas (Nitrogen and Air/Oxygen)
  - Computer with software readout



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Oxidative Inductive Time

- Relevant Standards:
  - ISO 11357-6:2008
  - ASTM D 3895-14/D 5885

- Important Notes:
  - *Can be done with High pressure DSC*
  - *Rate dependant*
  - *Fully Automated*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

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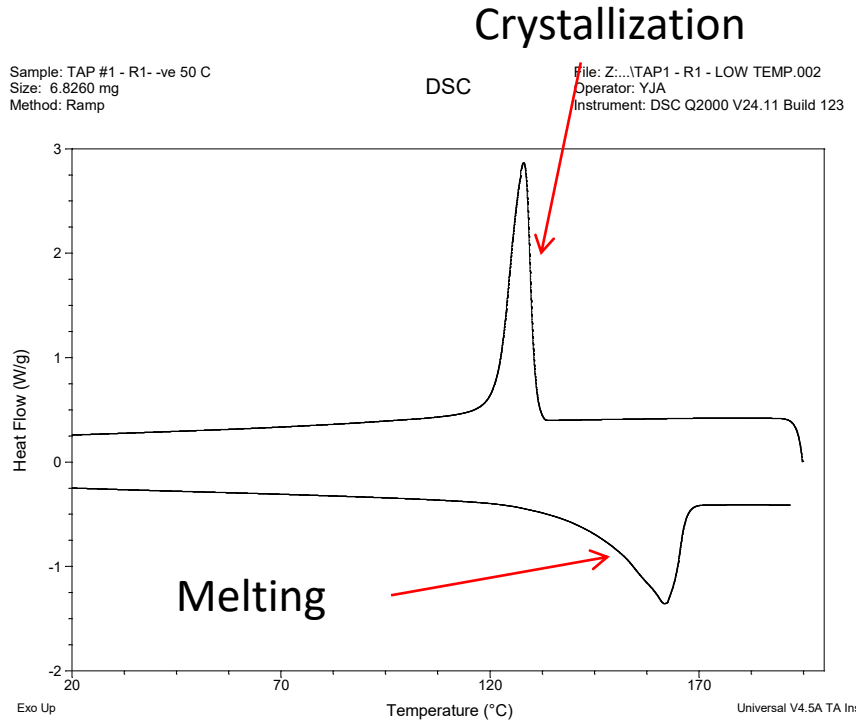
Melting and Crystallization

- Principle:
  - Measure the heat flow of polymer materials
- Importance:
  - QC Test to measure specific material property for a Quality check and processing
  - Determine processing conditions for polymers
- Equipment required:
  - TGA/DSC/SDT
  - Sample pans/cups
  - Purge gas (Nitrogen and Air/Oxygen)
  - Computer with software readout



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Melting and Crystallization

- Relevant Standards:
  - ISO 11357-3:2018
  - ASTM E794(06):2018/D 3418-15

- Important Notes:
  - *Rate Dependant*
  - *Sample mass consistency*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

Humidity Ageing

- Principle:
  - Refers to the stability of a material with increasing relative humidity conditions.
  - For transportation/Storage and Ageing
- Importance:
  - Material performance under changing conditions
  - Gives an idea for cyclic conditions to determine failure analysis
- Equipment required:
  - TGA/DMA Vapor Sorption
  - Nitrogen/Oxygen purge
  - Sample Pans
  - Computer/software readout
  - Autosampler

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Humidity Ageing

- Relevant Standards:
  - ISO 483:2008 and ISO/TC-61
  - ASTM D3045-18

- Important Notes:
  - *Thermal Analysis reduces this test to one simple test, reduces sample preparation.*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

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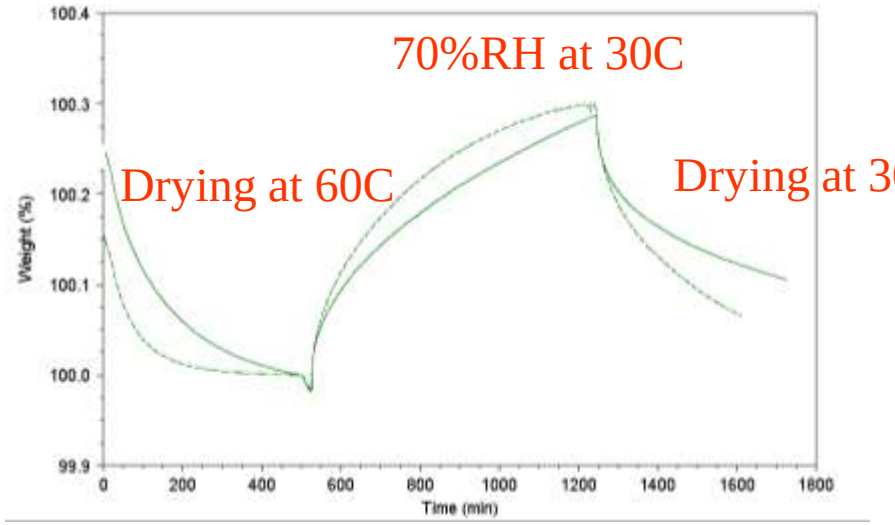
Water Adsorption

- Principle:
  - Monitoring whether a material is hydroscopic and hydrophilic behvior of raw material or finished product
- Importance:
  - Will determine material processing conditions to eliminate bubbling effect on finished material
  - Stability of material
- Equipment required:
  - TGA/DMA Vapor Sorption
  - Nitrogen/Oxygen purge
  - Sample Pans
  - Computer/software readout
  - Autosampler



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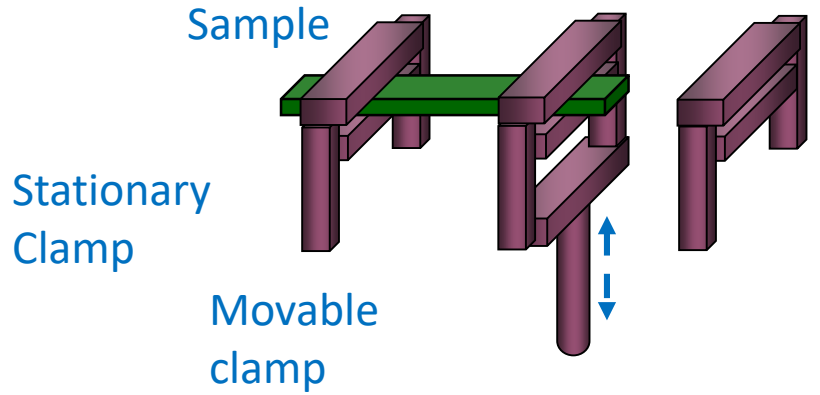
Water Adsorption

- Relevant Standards:
  - ISO 62:2008
  - ASTM D570

- Important Notes:
  - *Rate dependant*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

Stress Crack Resistance

- Principle:
  - Measures materials resilience to a constant stress under harsh environments
  - Environmental conditions are dependant on the end use of the material
- Importance:
  - Test looks at failure envelopes
- Equipment required:
  - DMA/Tensile Tester
  - Furnace/Chamber
  - Purge gases to create environment
  - Humidifier
  - Computer and software read out



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Stress Crack Resistance

- Relevant Standards:
  - ISO 22088-2:2006
  - ASTM D1693-15/D2561-17

- Important Notes:
  - *Type of environment*
  - *Constant load/stress*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

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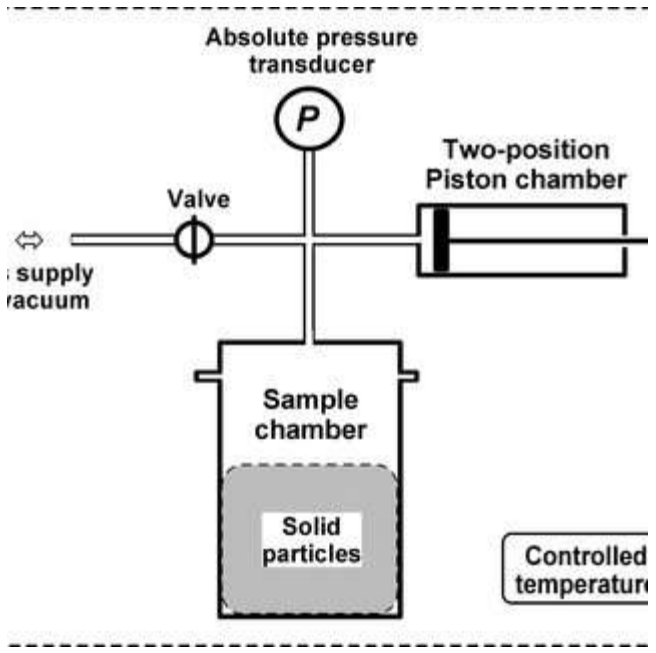
Bulk Density

- Principle:
  - The bulk density is given in g/ml. The bulk density depends on both the density of the particles and on the arrangement of the powder particles. The bulk density is influenced by the preparation, treatment and storage of the sample material.
- Importance:
  - Ensures for a working formulation
  - Homogeneity of finished sample depends on this
- Equipment required:
  - Pycnometer
  - Gas pycnometer



Bulk Density

- Relevant Standards:
  - ISO 1183
  - ASTM D792-13/D1475-13

- Important Notes:
  - *The surface tension of the liquid medium should be matched to the solid to avoid bubbling*
  - Adherence to standards
  - Sample preparation
  - Verification
  - Baseline
  - Calibration
  - Maintenance
  - Reporting

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Quality Control testing for the Pipe and Plastics Industry

Reza Theunissen (Instron)

Khanya Ngobo (TA Instruments)

Advanced Laboratory Solutions

SAPPMA Quality Workshop

advanced laboratory SOLUTIONS

Co-presented by Reza Theunissen and Khanya Ngobo
Product Specialists, Instron and TA Instruments

Ian Venter

10-04-2019

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SAPPMA Quality
The way beyond Certification

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10-04-2019

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The way beyond Certification

Passing the audit does not indicate that you are conversant in the standard.

E.G passing the school exams does not mean that you have become educated.

Knowing the syllabus requirements, you know that you can be asked any question, you did your homework, and you were fortunate that you could give the right answers to the questions.

You were not tested on the whole syllabus, only a sample.

You could have failed if other questions had been asked.

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The way forward (beyond) Certification

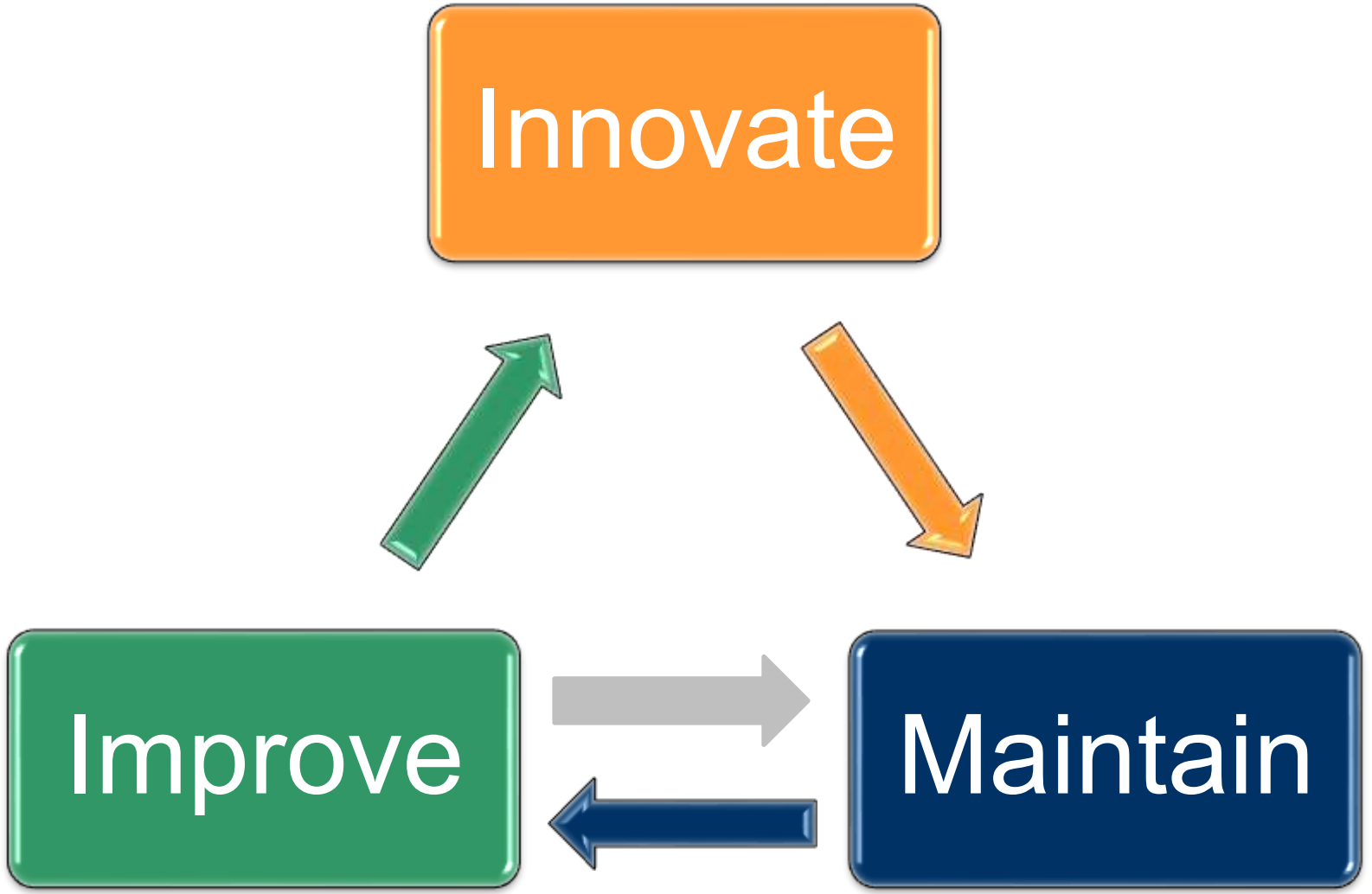
Certification implies that you have the capability to satisfy the requirements of your current customers, but this may not be sufficient to win business from your competitors.

You will need to do three things;

- Maintain (your standards)
- Improve (Efficiency and Effectiveness)
- Innovate (Innovate occasionally to set new standards)

(MII cycle; Innovate/Improve/ Maintain)

MII Cycle; Innovate/Improve/Maintain



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You will not know if you do not measure

If you do not build in a process of recording and tracking key critical to quality aspects (measuring your performance in key areas) prior to developing your quality system, you will not be able to compare your current results to the initial baseline.

Initial improvements are small and slow as you are still building your system and finding better ways of recording data.

What to expect as you follow the MII cycle

You may find an initial decline in performance (Slight)

A significant change can be expected in the performance values as they are becoming less erratic and less sensitive to changes in the organization or customer requirements.

Short term gains

Decline in reactive management (More predictable processes)

Decline in overtime (Less rework prior to deliveries)

Decline in design modifications (Well defined client needs)

Increase in orders (Updated Customer selection policies)

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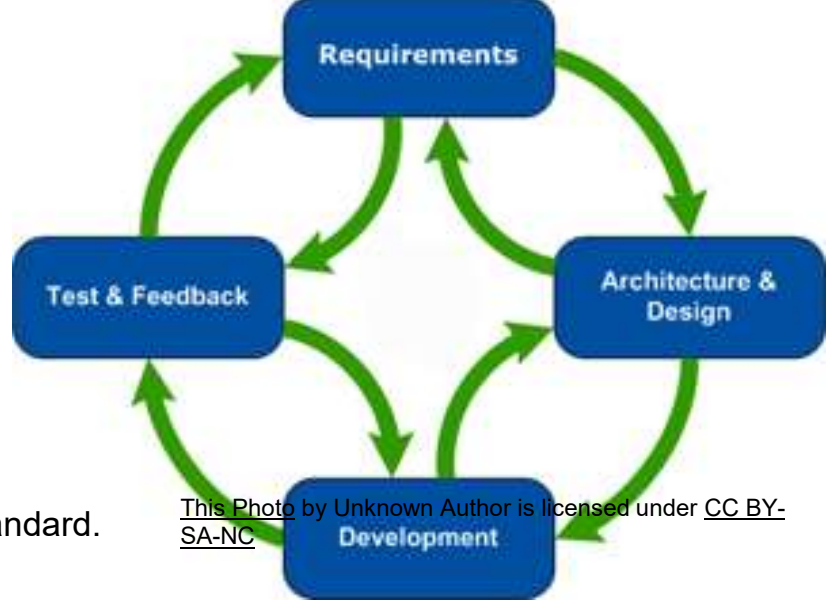
Continuing development



Many areas of the system needs to be developed.

System development never ceases if your company focus on market forces.

The initial assessment only took a sample of your operation to test it against a standard.

Subsequent audits will reveal more nonconformities and if not corrected will result in action that may include withdrawal of your certificate.

It is important to continue with any system development activities.

Every policy and requirement of every process needs to be tested over the range of operations to which it applies. With the result of opportunities for improvement.

Internal and external audits periodically conducted verify that you you remain compliant with requirements of the standards.

These audits only establish that you have retained the capability of meeting your customers requirements and that the systems are being implemented effectively.

The audits are not intended to address standards other than the one against which you were certified.

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Becoming more competitive and profitable

Key Factors on where action can be taken to improve competitiveness and profitability

- Reduction measures
- Increasing measures
- Stabilizing measures
- Keeping measures
- Improvements on Price
- Improvements on Timing
- Improvement on Productivity

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Reduction Measures

Many organizations have too much of what is not required to be profitable (Benefits can be derived from)

- Reduce complexity (fewer ways to doing something)
- Reduce variation (Consistent quality)
- Reduce waste (Keep resource costs low)
- Reduce Time (Reduction of bottlenecks)
- Reduce error in products, services, documents, decisions and communication. (Nett Cost Reduction)
- Reduce job classifications (Multi skilling)
- Reduce inspections (Reduction in costs)
- Reduce anti Quality attitudes (Jeopardizes cost saving opportunities)

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Increasing Measures

In some cases reduction would make things worse, thus you want to increase it for maximum benefit.

- Increase utilization of suitable materials, machines, tools, equipment, personal and facilities.
- Increase training of management and staff.
- Increase discipline and adherence to policies and practices.
- Increase tidiness and cleanliness.

- Increase availability and retrievability of information.
- Increase motivation of management and staff.

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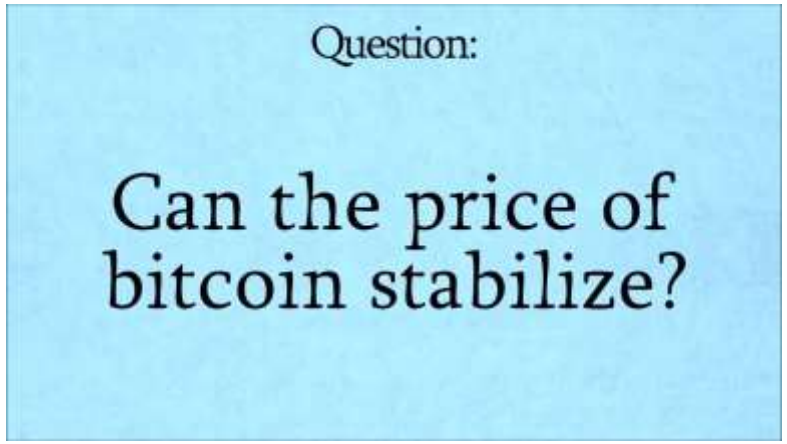
Stabilizing Measures

Before compliance systems were in place performance was erratic, although it may be more stable now it will need more effort to make it stable

Aspects to address;

- Stabilize control processes – less corrections required.
- Stabilize methods – Standardize on one method throughout the organization when it is found to work.
- Stabilize variation in materials so that you have less variations costs.
- Stabilize suppliers so you depend on fewer but more reliable suppliers.
- Stabilize processes so that variation is predictable.
- Stabilize the environment to reduce the effect that variation might have on operations.



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Keeping Measures

Many obsolete documents were removed, over and above documents you have several things you need to keep, this may though not be in document form.

Some important things to keep;

Keep commitments to show workforce that you are serious about quality.

Keep records so you do not have to rely on opinions.

Keep measuring performance so you know where you are at any time.

Keep analyzing results so that you know what to fix, what is about to happen and what has happened.

Keep on auditing, so you can determine the health of your organization.

Keep questioning the status quo as nothing stands still.

Keep reducing, increasing and stabilizing.

Keep maintaining, improving and innovating.

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Improvements on Price

Price is a function of

Cost /Profit and what the market is willing to pay

You can offer price reductions to customers as a result of making your process more efficient.

Remember if you control change you control cost, so the more stable your process the less they cost.

Look for alternative approved resources, alternative materials, alternative methods, consider alternative designs. Price remains a powerful driving force.

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Improvements on Timing

Always monitor the cycle time of the major processes and also include non production processes.

Often other processes are source rich in cycle time improvements such as the time to change a document a design a policy, etc.

Time taken to place an order, arrange training, authorize budgets and expenditure.

Reaction time is also important especially for maintenance to equipment, customer support, and problem solving. How long does it take for your management team to react to a situation of importance. We all know of perceived priorities, question them if they hinder continuous improvement.

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Improvement on Productivity

General aims

Improve product quality

Increase productivity

Reduce cost of development, manufacture and service delivery.

Productivity is not easy to measure unless you have one product on one production line

Multiple products on multiple lines each at a different stage of maturity makes comparisons more complicated but not impossible if you know what to focus on.

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Remember quality is your friend.

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SAPPMA Quality Workshop II

Co-presented by Justin Marsberg and Francois Prinsloo

Ian Venter

17-07-2019

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SAPPMA Quality Workshop II
Summary of Workshop I

Ian Venter

17-07-2019

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Pipe Systems

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17-07-2019

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Understanding Conformancy

- Conformity assessments quality marks, and quality product are often not well understood.
- To better understand the above we need to focus on what our end goal is, focus driven processes and systems that achieve quality infrastructure.
- Let us look closer at what quality infrastructure comprise of. For the purpose of this document we look at quality infrastructure as three inseparable parts of a whole.

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Quality Infrastructure

- **Standardization.** To improve economic efficiency and to give access to world markets
- **Metrology.** The ability to make reliable measurements
- **Conformity assessment**. The ability to demonstrate that items conform to the requirements specified in the standards

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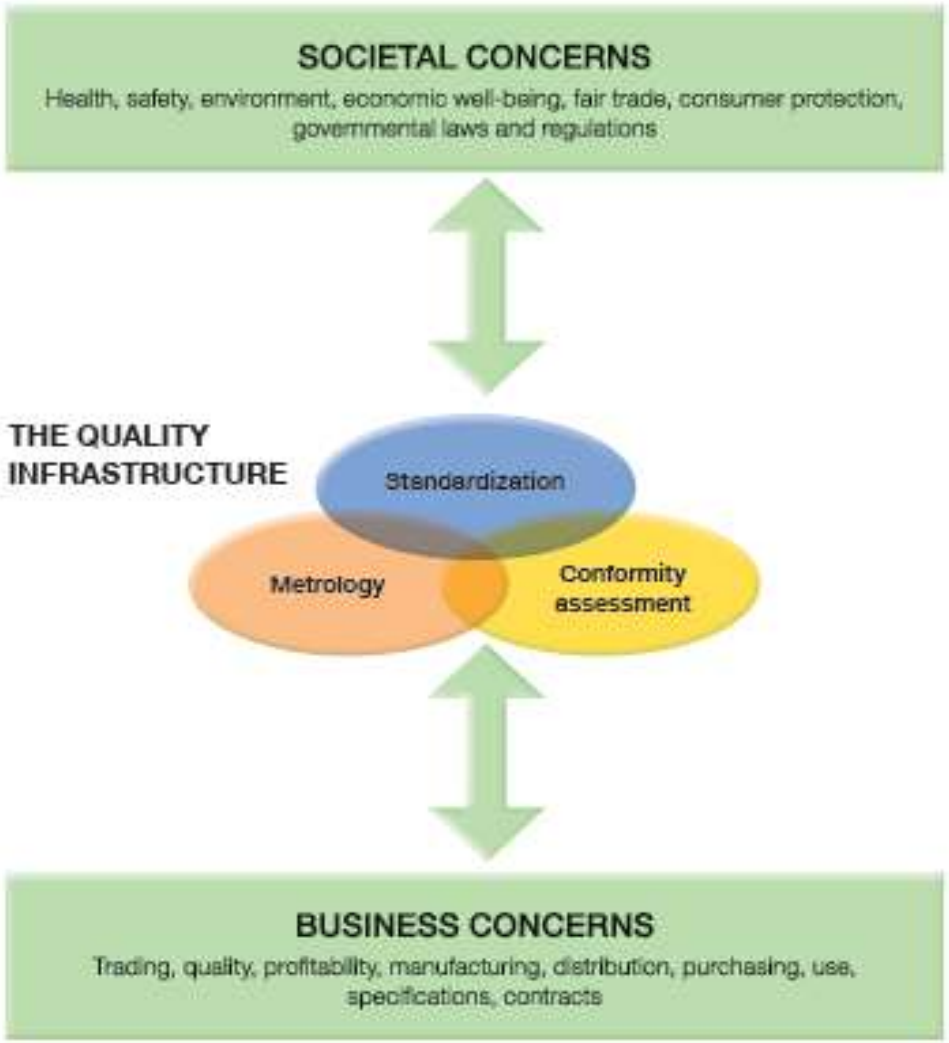
The Quality Infrastructure Challenge



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Why Quality Infrastructure

- The establishment of a Quality infrastructure is a key step in the development of any country.
- Quality infrastructure is the system of technical capabilities used to raise the quality of goods imported traded and exported.
- Quality infrastructure is used to protect markets, businesses and consumers and enables countries to integrate into the global trade system.

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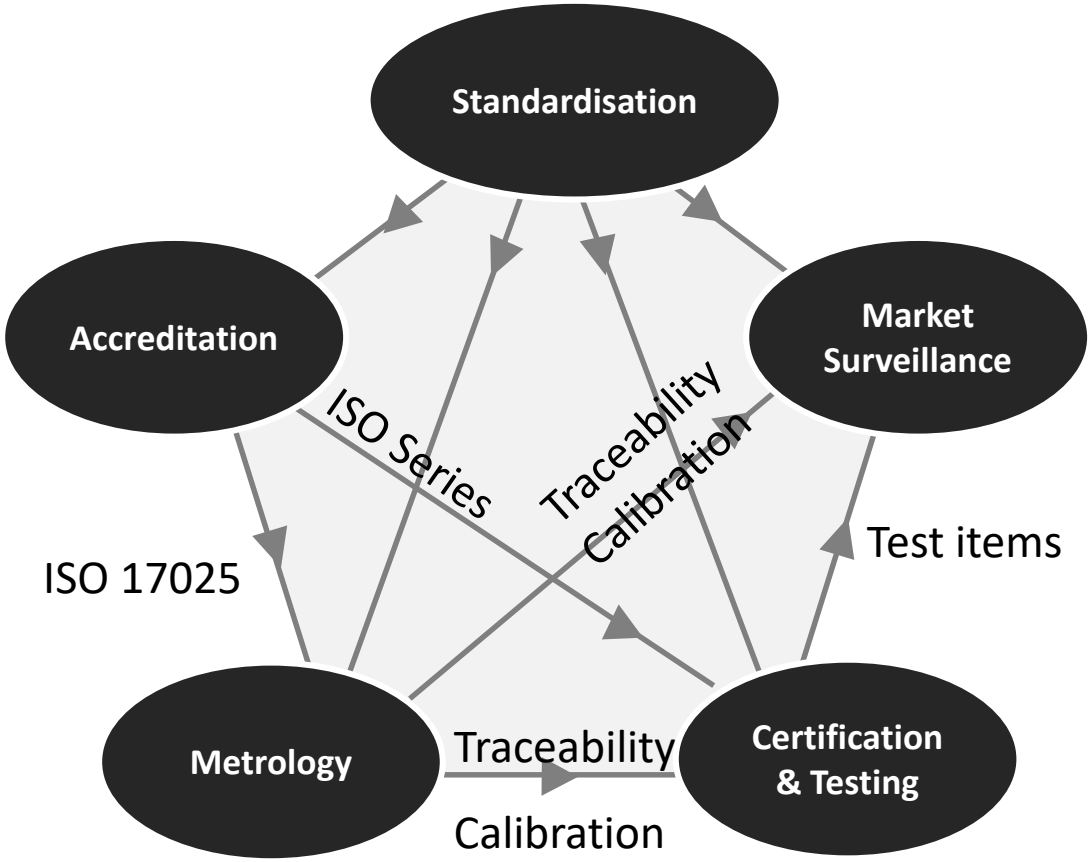
Integration of Conformance into a process forming a system



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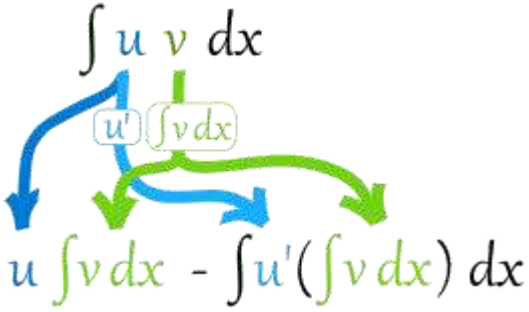
Purpose and Objective of conformance integration

- Once standards have been adopted responsible bodies need to assess the performance of goods to determine if they conform to relevant standards.

- Without effective conformity assessment standards have very little value.

- A conformity scheme is a regularized way of undertaking conformity assessment and then certifying the results.



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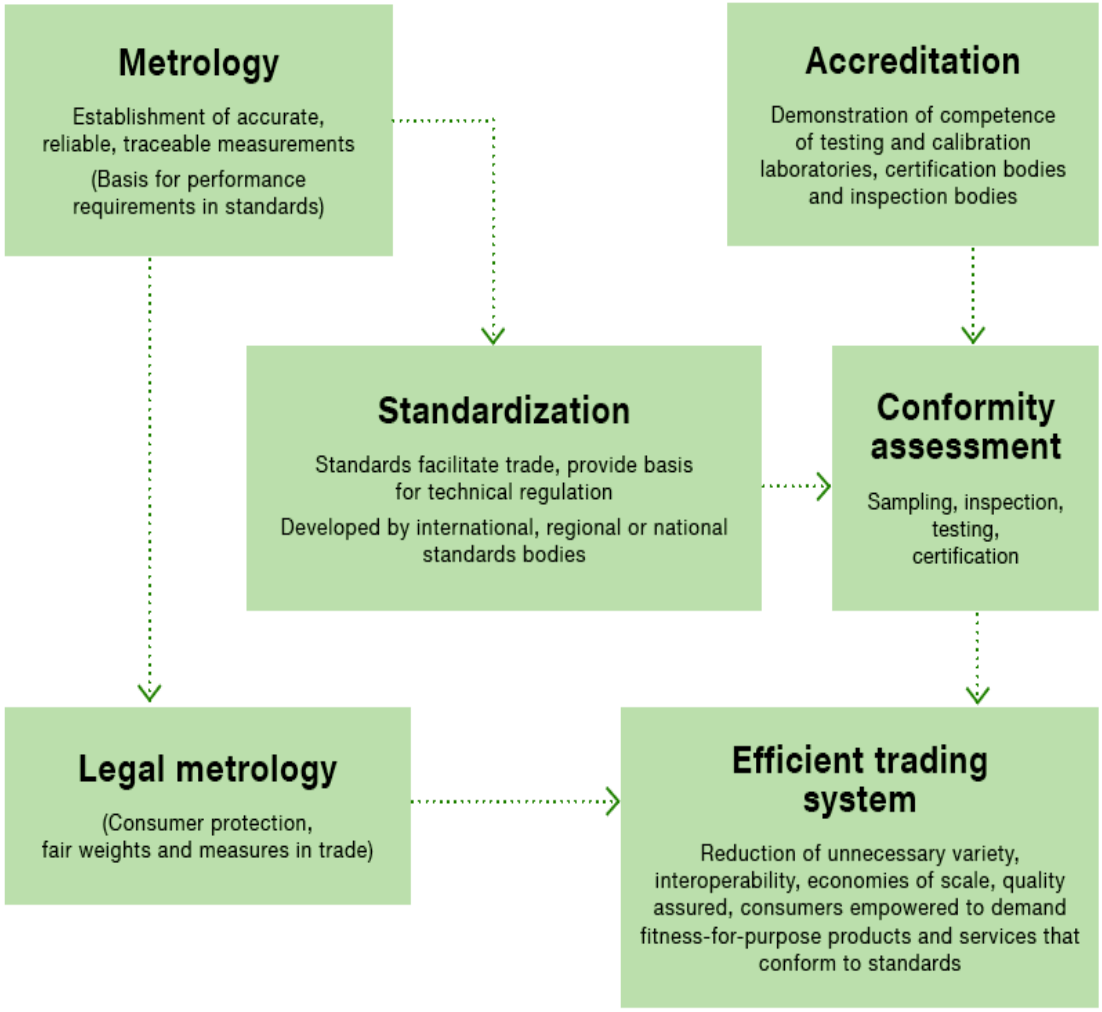
Conformance System



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The need for Conformance

- Conformancy assessment and its consequences have been around for a very long time
- It formed an important part of trade and industry, a good example is the weight of a loaf of bread. Most can still remember how the public responded to the know-how that the bread were lighter than claimed on the package.
- Conformity assessment is of utmost importance when we are protecting people property and the environment, this holds true especially in the potable water industry.
- Dangerous applications with the potential loss of lives even more so requires robust conformancy assessment schemes, one such application that comes to mind is pressure gas systems.

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The need for Conformance

- Conformity schemes enable products to be certified as meeting standards.
- Goods are required to show evidence of conformity to standards, thus does it perform and does it comply to the standard?
- Conformity assessment is the process of assuring that product, systems and personnel meet the requirement outlined in the conformity scheme.
- A technical document that outlines requirements for products, systems, or personnel to meet specified standards under certain inspection and testing regimes need to be specified and shall include reference to the Standards, Inspection Regime, Testing Regime and conformancy Scheme.

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NB: You drive Conformance

- An important note to consider is that Certification as a result of a successful conformity assessment and product marking as outcome, may not satisfy the end user specific needs.
- Reason being that the certification body may not have an adequate understanding of the Standard, product and or system requirements of importance to make it add value to the Quality Infrastructure environment.
- Certification bodies are not experts in the products and or the systems and need assistance from subject matter experts to drive the content of the conformity schemes.
- To date this was left to the certification bodies.

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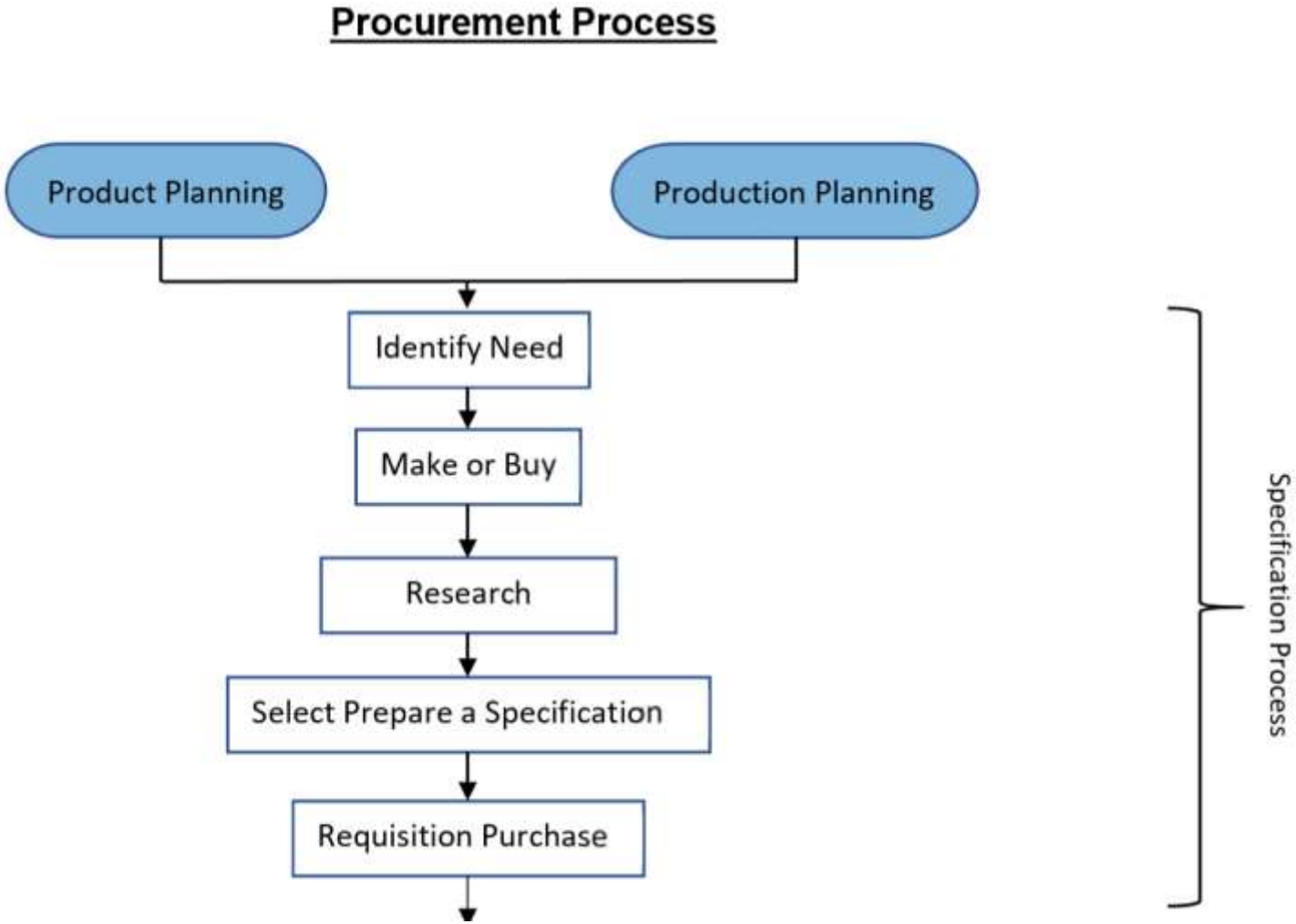
Your Role in Conformance



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Your Role does not stop after Specification

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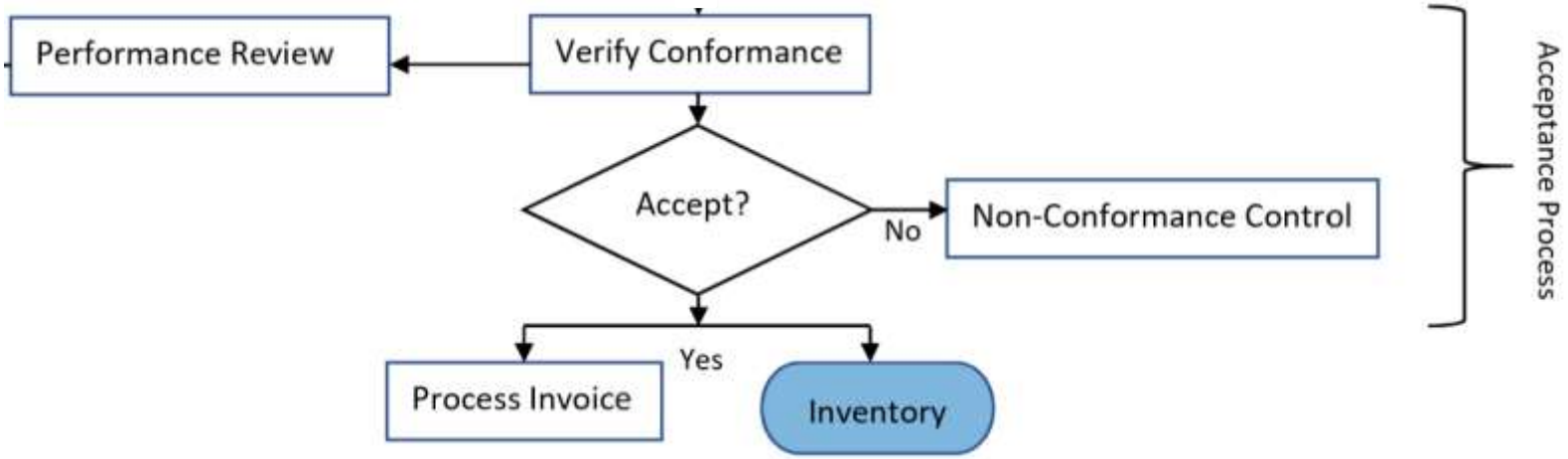
Acceptance Process must be driven by the Specification



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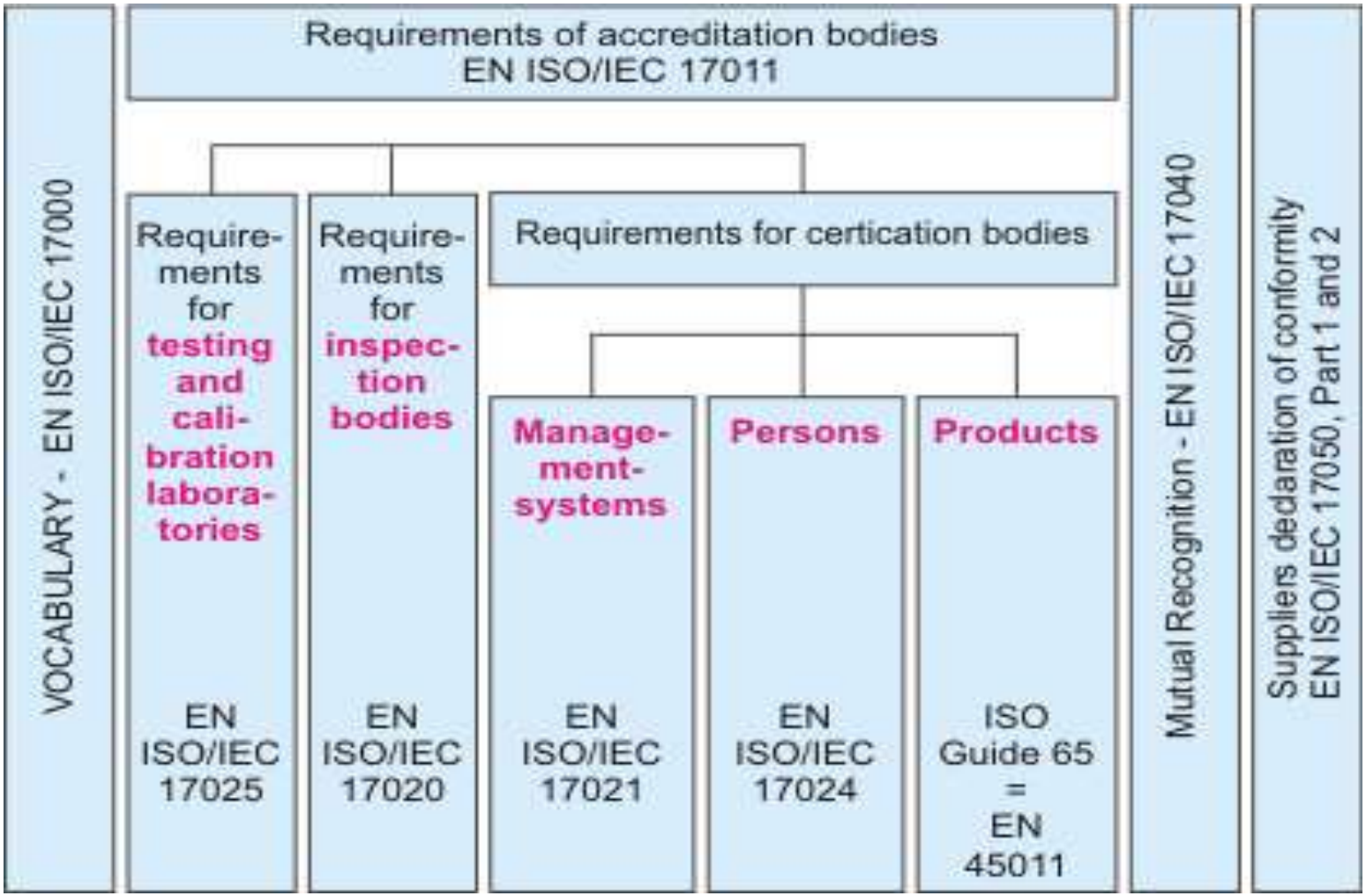
Elements of conformity



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The Elements of Conformity assessment need to be understood.

Definition of conformity assessment: Conformity Assessment is defined in ISO/IEC 17000 as;
The demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

i.e. does the product fulfil these requirements

<u>Conformity Assessment is not the evaluation of the quality of a product, process or system</u>

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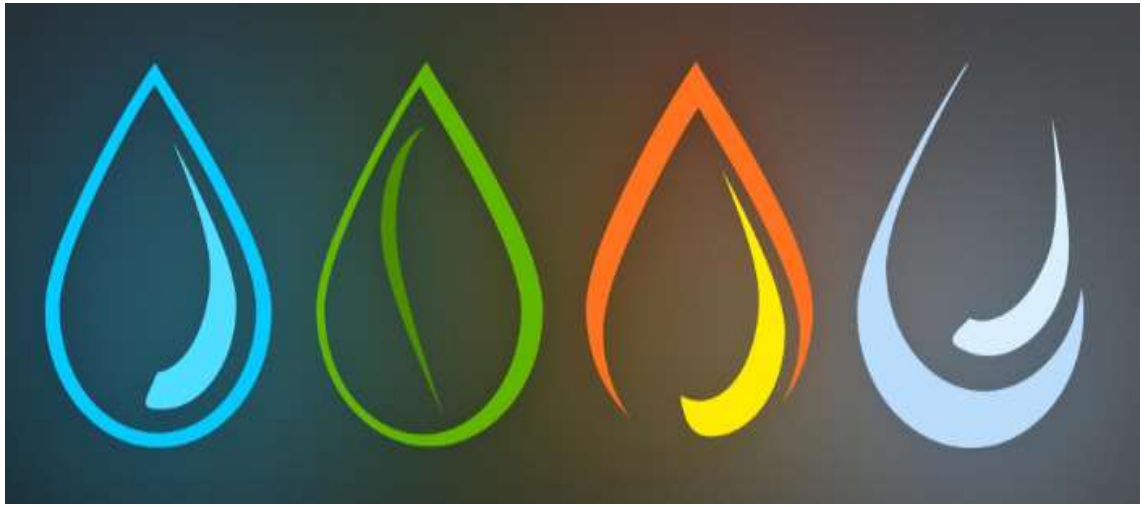
The Elements of Conformity assessment need to be understood.

Definition of conformity inspection: Inspection is defined in ISO/IEC 17000 as; The examination of a product design, product, service, process or plant/installation, and determination of the conformity with specific requirements or, on the basis of professional judgement, general requirements.

The results of inspection may be used to support certification



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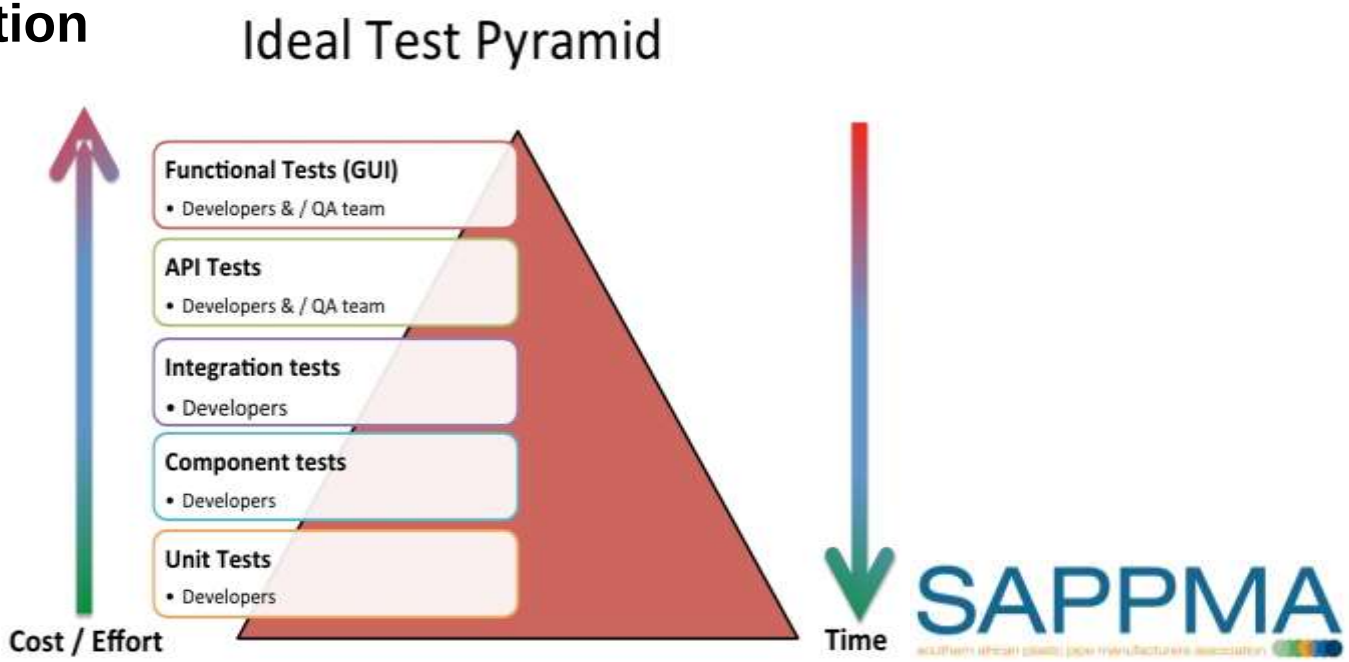
The Elements of Conformity assessment need to be understood.

Definition of testing: Testing as defined in ISO/IEC 17000;

Testing: Determination of one or more characteristic s of an object of conformity assessment according to a procedure

Procedure: Specified way to carry out an activity or a process

The results of inspection may be used to support certification



The Elements of Conformity assessment need to be understood.

The definition of certification: Certification as defined in ISO/IEC 17000;

Certification: Third-party attestation related to products, processes, systems or persons

A certificate is not a test report

Attestation: The issue of a statement by an organization that they have undertaken review(assessment) to verify that a product etc. has demonstrated compliance (conformity) with particular requirements set out in the conformancy scheme documents and related standards etc.

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Certification Schemes

- Let us look at a variety of certification schemes that exists;

- Accredited VS Non-Accredited
- Regulated VS Non-Regulated
- Compulsory VS Non-Compulsory
- National, Regional, International

- Schemes that allow or mandate the use of a product certification mark and others don't.

- Compulsory certification does not have to be entirely handled by government authorities. Certification can be issued on the basis of reports from accredited private laboratories.

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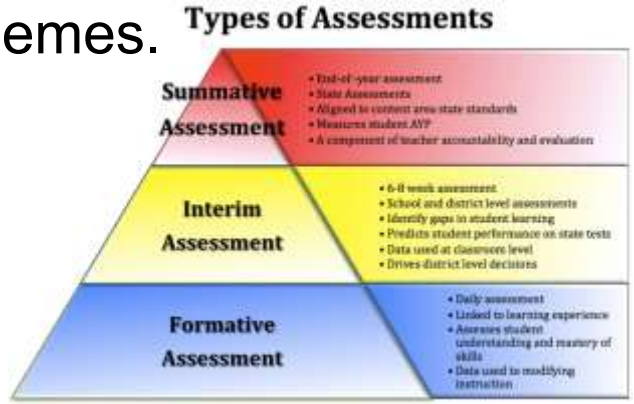
Guidance standards for Conformancy assessment

- Fortunately there is some guidance out there: ISO/IEC 10765 and 10767

- ISO/IEC 17065; Conformity assessment – Requirements for bodies certifying products, processes and services

- ISO/IEC 10767; Conformity assessment- Fundamentals of product certification and guidelines for product certification schemes.



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NB: Understand your Conformance objectives

- Have realistic objectives- How much testing do we want to do on a regular basis, what is practice and affordable?

- Remember certification bodies do not automatically understand or know your specific system needs, and will from a content point of view only have the minimum required assessment fundamentals to be able to be certified as a certification body.

- It will be important that you familiarize yourself with the assessment fundamentals of your suppliers certification bodies to ensure that the criteria of importance to your system as a minimum is covered.

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Product Quality

- As it is now quite clear that certification does not deal with product or service quality, it will be of importance to focus more attention on control systems for product and services.

- Over and above the above stated information, it will be of importance to understand if the manufacturers PQP Product Quality Plans are in line with sound quality principles and standards and to ensure that they are included per product standard in the Quality Management system SANS ISO 9001 of each manufacturer or supplier of goods or services.

- Each manufacturer supplier of goods needs to have a $QCP_{(Manufacturer)}$ Quality Control Plan in line with its capabilities to ensure that compliant products are shipped and supplied.

- All recipients of products and services need to have in place a
- $QCP_{(Purchaser)}$ Quality Control Plan aligned with the capabilities of its suppliers of product and services to ensure compliance to specification.

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Questions and Answers

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