

**NATIONAL CONFERENCE ON
QUALITY ASSURANCE FOR HIGHER
EDUCATION INSTITUTIONS IN
MALAWI**



**9TH AUGUST 2017 – SUNBIRD NKOPOLA,
MANGOCHI**





QUALITY MANAGEMENT SYSTEMS BASED ON ISO 9001:2015

A BRIEF OVERVIEW
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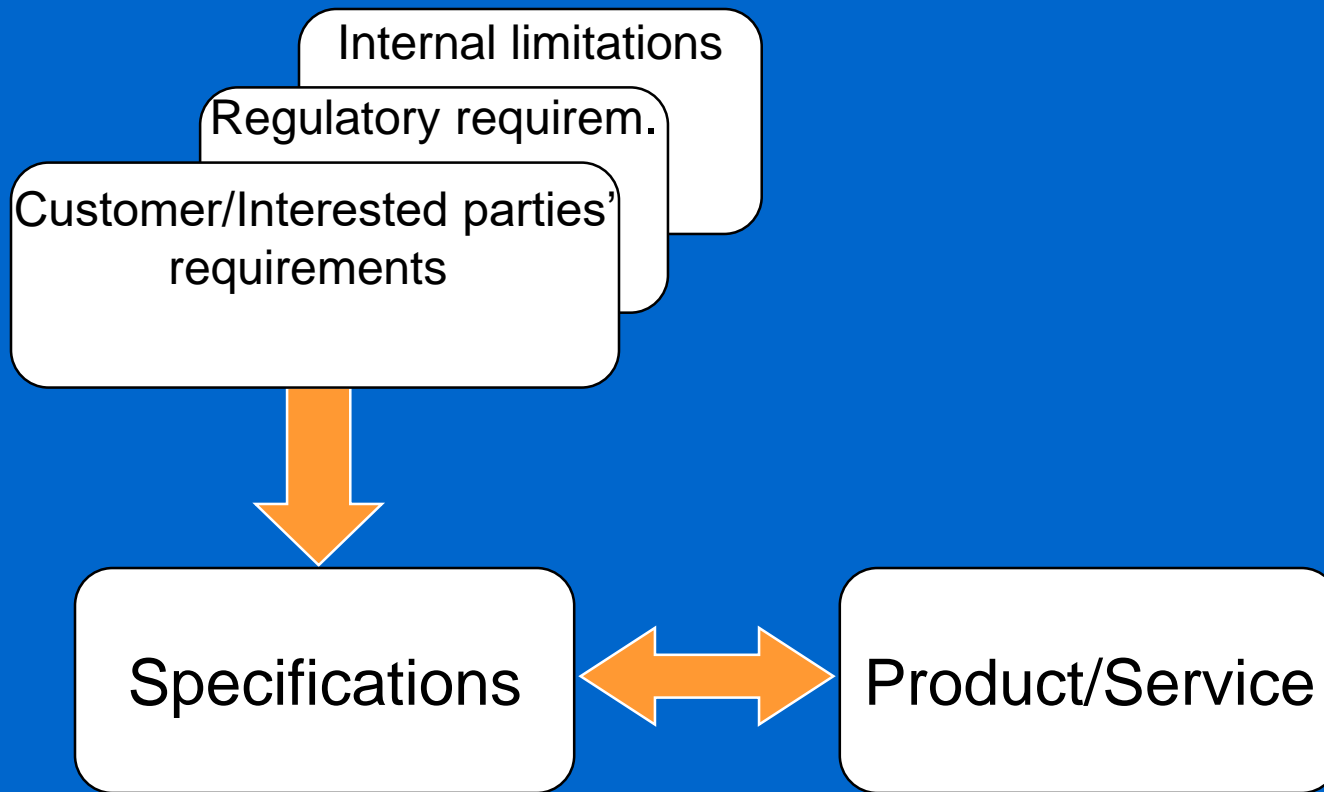
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What is quality?



The 2 dimensions of quality





The 8 dimensions of quality (1)

- a) **Performance**: Does the product or service do what it is supposed to do, within its defined tolerances?
- b) **Features**: Does the product or service possess all of the features specified, or required for its intended purpose?
- c) **Reliability**: Will the product or service consistently perform within specifications?
- d) **Conformance**: Does the product or service conform to the specification?





The 8 dimensions of quality (2)

- e) **Durability**: How long will the product perform or last, and under what conditions?
- f) **Serviceability**: Is the product relatively easy to maintain and repair?
- g) **Aesthetics**: The way a product looks is important to end-users.
- h) **Perception**: Perception is reality. The product or service may possess adequate or even superior dimensions of quality, but still fall victim to negative customer or public perceptions.





Quality attributes in relation to:

Service industry – High Education

- Contents of the service
- Competence
- Accessibility
- Reliability
- Understanding customer needs
- Friendliness, politeness
- Time of delivery
- Personal contact, confidence
- Environment
- Reputation





Definition of Quality (1)

“Doing the right thing right, right away.”

The most comprehensive and perhaps the simplest definition of quality is that used by advocates of total quality management (W. Edwards Deming, 1982)



Definition of Quality (2)



Degree to which a set of
inherent characteristics of an
object fulfils requirements

(Ref.: Clause 3.6.2 of ISO 9000:2015)



Process

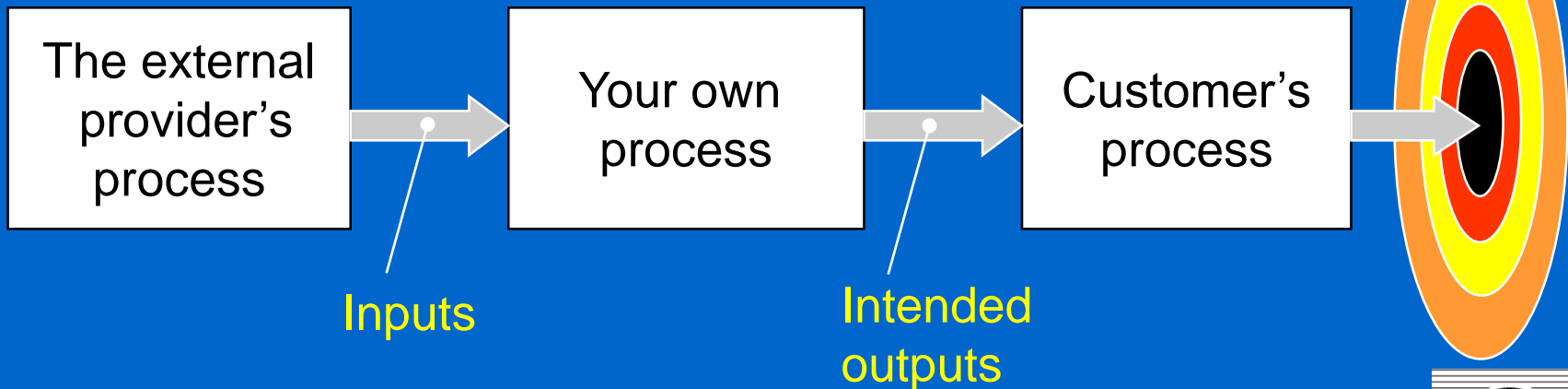


Set of interrelated or
interacting activities that
use inputs to deliver an
intended output

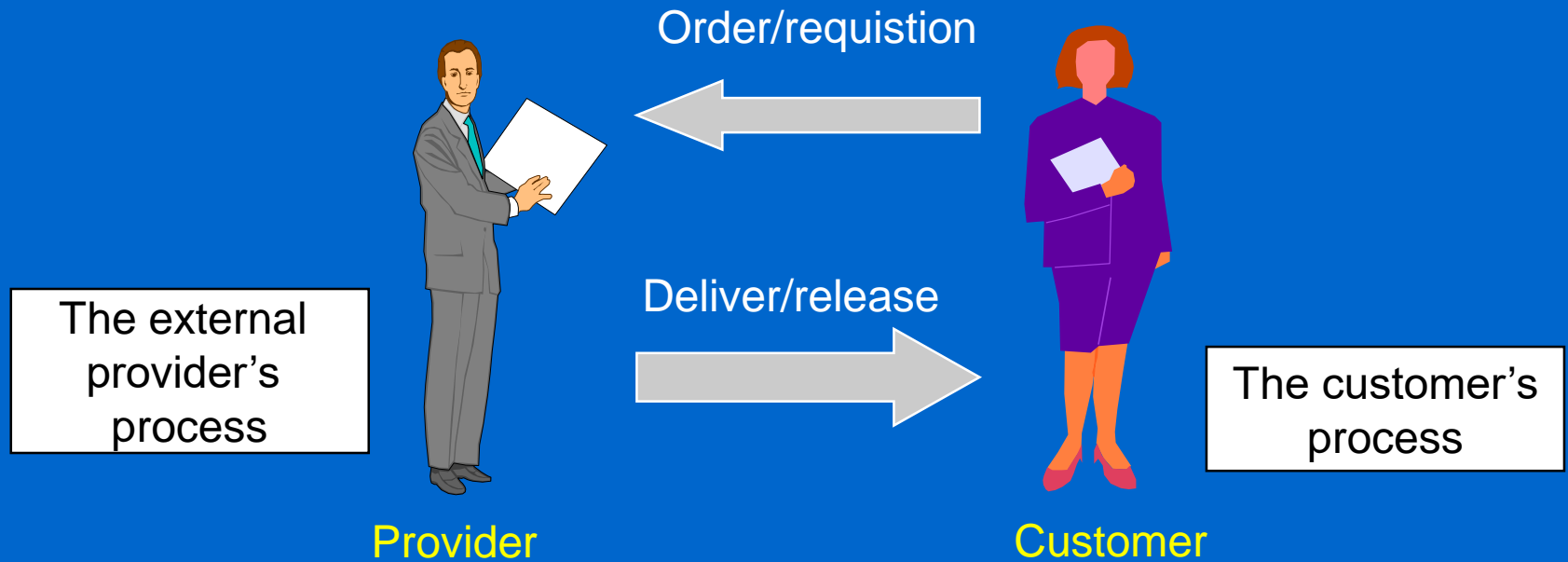
(Ref.: Clause 3.4.1 of ISO 9000:2015)



The process approach to customer satisfaction



Who is your customer?



Who is your customer?

- External customers: Outside the organisation
- Internal customers: Within the organisation



Customers and interested parties



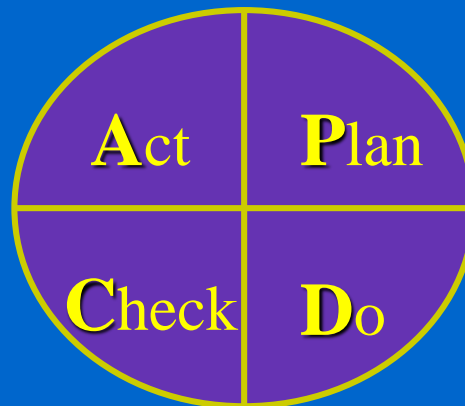
- Customers and consumers (end-users)
- People in the organization
- Owners/investors, including the public sector
- Suppliers and partners
- Society at large and the public affected by the organization and its products



Process approach in PDCA context



- The process approach involves the systematic definition and management of processes and their interactions in order to achieve intended or desired results in accordance with QMS requirements and strategic intent of an organisation
- Use of the **PLAN-DO-CHECK-ACT (PDCA) cycle** enhances implementation of the process approach in an organisation



Application of the PDCA cycle in QMS development and implementation



- **PLAN:**
 - a) Establish objectives of the intended system and its processes;
 - b) Establish resources needed to deliver intended or desired results in accordance with set requirements;
 - c) Identify and address risks and opportunities.



Application of the PDCA cycle in QMS development and implementation



- **DO:**

- a) Implement as planned.

- **CHECK:**

- a) Monitor and measure against policies, objectives, requirements and planned activities:

- i. Processes;

- ii. Resulting products and services

- b) Report results from monitoring and measuring activities



Application of the PDCA cycle in QMS development and implementation



- ACT: Where necessary
 - a) Take appropriate action(s) to improve performance of processes, products and the whole QMS.



Continual improvement (Clause 10.3)



- Corrective action:
 - i. To prevent recurrence of non-conformities;
 - ii. Shall be appropriate to the effects of the non conformities encountered.
 - iii. Shall be reviewed for effectiveness.
- Preventive action:
 - i. To prevent potential non-conformities, notably serious ones.
 - ii. Uses risk analysis
- Improvement
 - i. Breakthrough improvement
 - ii. Small-step improvement within existing processes



Improvement requires a change of human attitudes



From:

1. Vagueness
2. Decisions based on opinions
3. Seeing only *your* side
4. Final inspection
5. Errors are punished
6. Renounce responsibility
7. The manager decides
8. The customer has to accept our solution
9. Detailed instructions
10. Surveillance

To:

1. Orderliness
2. Decisions based on facts
3. Co-operation across borders
4. Planning and prevention
5. Understand and learn from errors
6. Active participation and willing to take responsibility
7. The manager points out directions
8. We are directed by customer needs
9. Understanding and independence
10. Govern your own work





Quality management therefore is:

Coordinated activities to direct and control an organization



Management



Note 1: Management can include establishing policies and objectives, and processes to achieve these objectives

Note 2: The word “management” sometimes refers to people i.e a person or group of people with authority and responsibility for the conduct and control of an organisation. When “management” is used in this sense, it should always be used with some form of qualifier, eg “Top management” to avoid confusion with the concept of “management” defined above.

(Ref: Clause 3.3.3 of ISO 9000:2015)





Quality management



Ref. ISO 9000:2015



Quality management principles

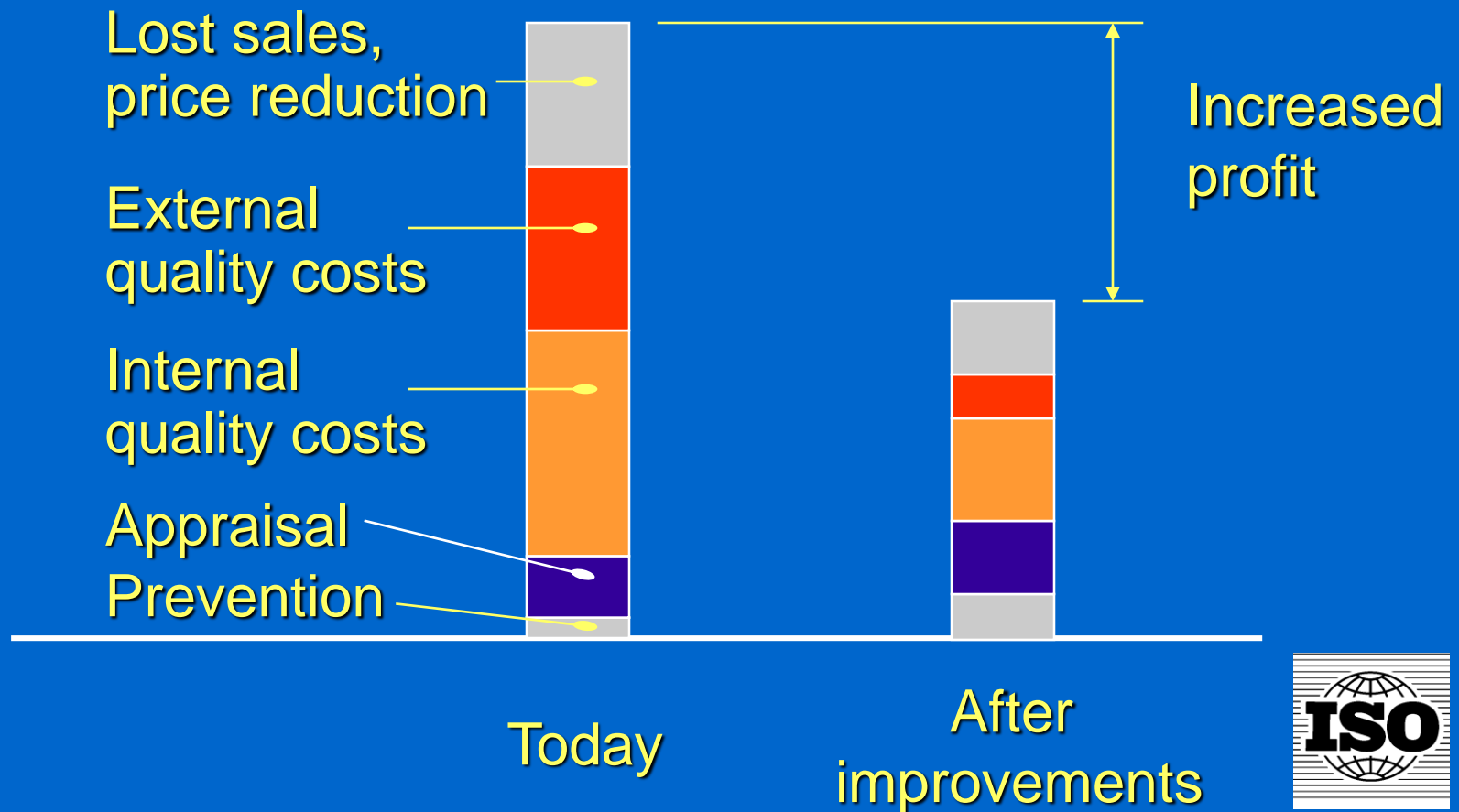


1. **Customer focus:** The primary focus of quality management is to meet customer requirements and to strive to exceed customer requirements.
2. **Leadership:** Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives.
3. **Engagement of people:** Competent, empowered and engaged people at all levels in an organisation are essential to achieve desired outputs.
4. **Process approach:** Consistent and predictable results are achieved more effectively and efficiently when activities are managed as interrelated processes that function as a coherent system
5. **Improvement:** Successful organisations have an ongoing focus on improvement.
6. **Evidence-based decision making:** Decisions based on analysis and evaluation of data and information are more likely to produce desired results.
7. **Relationship management:** For sustained success, organisations manage their relationships with relevant interested parties, such as providers.



(Ref: Clause 2.3 of ISO 9000:2015)

Does quality management pay?





Benefits of Quality Management

- Improved internal working leading to less errors and re-work.
- Improved customer satisfaction and loyalty.
- Improved morale and motivation.
- Competitive advantage.
- Increased profitability.
- Enhanced status/image.
- Preferential insurance premiums.



Why Implement ISO 9001 standard



- If an organisation:
 - a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; and
 - b) Aims to enhance customer satisfaction through effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements



What type of organisations should implement ISO 9001 standard?



- All the requirements of ISO 9001 standard are **generic and are intended to be applicable to any organisation**, regardless of its type or size, or the products and services it provides



Understanding the organisation and its context (Clause 4.1)



- The organisation SHALL:
 - a) Determine external and internal issues that are relevant to its purpose;
 - b) Monitor and review information about these external and internal issues



Determining the scope of the quality management system (Clause 4.3)



- To establish the scope of the quality management system, the organisation SHALL:
 - a) Determine the boundaries and applicability;
 - b) Consider requirements in clauses 4.1 and 4.2;
 - c) Consider its products and services;



Determining the scope of the quality management system (Clause 4.3)



- The scope of the quality management system SHALL:
 - a) State the types of products and services covered;
 - b) Provide justification for exclusion of any requirement(s) of ISO 9001 from the scope



Quality management system and its processes (Clause 4.4)



- The organisation SHALL:
 - a) Determine the processes needed for its quality management system; and
 - b) Determine their application throughout the organisation



Quality management system and its processes (Clause 4.4)



- The organisation SHALL:
 - a) **Maintain documented information** to support the operation of its processes;
 - b) **Retain documented information** to provide evidence that the processes are implemented as planned.





Management and leadership

- *Management:*
The art of coping with complexity
- *Leadership:*
The art of coping with change

Ref.: John P. Kotter (1990)



Management



- Motivate people
- Direct and control processes
- Provide and balance resources
- Organize the resources
- Encourage improvement



Leadership



- Leading change
- Break old habits
- Set a vision
- Develop the strategy
- Overcome the resistance to change



Leadership and commitment (Clause 5.1)



- Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organisation's quality objectives.
- Top management SHALL demonstrate leadership and commitment with respect to:
 - a) The quality management system; and
 - b) Customer focus



Leadership and commitment to customer focus (Clause 5.1.2)



- The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations
- Top management SHALL ensure that:
 - a) Customer and applicable statutory and regulatory requirements are **determined, understood and consistently met;**
 - b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are **determined and addressed;**
 - c) The focus on enhancing customer satisfaction is **maintained.**



Resources (Clause 7.1)



- The organisation SHALL determine, provide and maintain the following resources:
 - a) **People:** Persons necessary for effective implementation of the system and for operation and control of processes;
 - b) **Infrastructure:** Infrastructure necessary for the operation of processes and achieve conformity of products and services;
 - c) **Environment:** Environment necessary for the operation of processes and achieve conformity of products and services;
 - d) **Monitoring and measuring resources:** Resources needed to ensure valid and reliable results when monitoring or measuring is used to verify conformity of products and services to requirements
 - e) **Organisational knowledge:** Knowledge necessary for the operation of processes and to achieve conformity of products and services



Measurement traceability (Clause 7.1.5.2)



- Measuring equipment SHALL be:
 - a) **Calibrated or verified**, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;
 - b) **Identified** in order to determine their status;
 - c) **Safeguarded** from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results



Competence (Clause 7.2)



The organisation SHALL:

- a) Determine the necessary competence of person(s) doing work under its control that affects desired outputs;
- b) Ensure that the person(s) are competent on the basis of appropriate education, training, or experience;
- c) Where applicable, take actions to acquire the necessary competence, and shall evaluate the effectiveness of the actions;
- d) Retain appropriate documented information related to competence



What is competence?



The ability to apply knowledge and skills to achieve intended results

Note: Demonstrated competence is sometimes referred to as qualification

(Ref. Clause 3.10.4 of ISO 9000:2015)



Awareness (Clause 7.3)



- Persons doing work under the organisation's control SHALL be aware of:
 - a) The quality policy;
 - b) Relevant quality objectives;
 - c) Their contribution to the effectiveness of the quality management system;
 - d) The implications of not conforming with the quality management system requirements



Operational planning and control



(Clause 8.1)

- In an endeavour to meet requirements for provision of products and services, the organisation SHALL:
 - a) Determine the requirements for the products and services;
 - b) Establish criteria for
 - i. Processes;
 - ii. Acceptance of products and services;
 - c) Determine the resources needed to achieve conformity to the products and service requirements;
 - d) Implement control of processes in accordance with the criteria;
 - e) Determine, maintain and retain necessary documented information



Control of externally provided processes, products and services (Clause 8.4.1)



For externally provided processes, products and services, the organisation SHALL:

- a) Ensure that they conform to requirements (Q-Whose requirements?????);
- b) Determine the controls to be applied to them.



Control of externally provided processes, products and services (Clause 8.4.1)



Based on the ability of external providers to provide processes, products and services in accordance with requirements, the organisation SHALL determine and apply criteria:

- a) For **evaluation** of external providers;
- b) For **selection** of external providers;
- c) For **monitoring of performance** of external providers; and
- d) For **re-evaluation** of external providers.



Identification and traceability



(Clause 8.5.2)

- The organisation's **outputs SHALL be identified by use of suitable means**, where it is necessary to ensure the conformity of products and services;
- The **status of outputs SHALL be identified**, based on monitoring and measurement requirements, **throughout production and service provision**;
- The **unique identification of the outputs shall be controlled** when traceability is a requirement;
- **Documented information** necessary for traceability **shall be retained**.



Release of products and services (Clause 8.6)



- The organisation SHALL:
 - a) **Verify**, at appropriate stages, that the product and service requirements have been met;
 - b) **Not proceed to release** products and services to the customer until planned arrangements have been satisfactorily completed;
 - c) **Retain documented information** related to the release of products and services :
 - i. As evidence of conformity with acceptance criteria;
 - ii. For traceability to person(s) authorizing release.



Control of non conforming output (Clause 8.7.1)



- The organisation SHALL:
 - a) Identify and control outputs that do not conform to requirements to
 - i. Prevent unintended use;
 - ii. Prevent unintended delivery.
 - b) Take appropriate action on outputs based on the nature of the non conformity and its effect on the conformity of products and services





THANK YOU

