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Congratulations
UiTM Medical Faculty

Malaysia's
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Transplant Centre

First Kidney Transplant performed
in UiTM **14th November 2017**
in collaboration with UM

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From: The Vice Chancellor

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institute of quality and knowledge advancement

HOME   ABOUT INQKA ˅   QSOE ˅   IQA ˅   QUALITY AWARDS ˅   WEB MEDIA UITM ˅   SYSTEMS ˅   DOWLOAD ˅   CALENDAR

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158
2018 overall rank

WE ARE
THE TOP 1.3%
UNIVERSITIES
IN ASIA

181
2016/2017 overall rank

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QS UNIVERSITY RANKINGS ASIA

ISO 9001 : 2015 Awareness

Presented by:

**Tuan Syed Abdul Illah Alyahya Syed Abd Kadir
Centre of Foundation Studies**

18 July 2018

| TIME	ACTIVITY
8.30 – 8.55 am	Registration
9.00 – 9.30 am	Introduction to course objectives, background of ISO and QMS
9.30 – 10.00 am	Introduction to ISO 9001:2015
10.00 – 10.30 am	Background of changes & process approach
10.30 – 10.45 am	Break
10.45 – 12.45 noon	Understanding ISO 9001:2015 requirements – Clauses 1- 7
12.45 – 2.00 pm	LUNCH BREAK

PROGRAM ITINERARY

TIME	ACTIVITY
2.00 – 3.15 pm	Understanding ISO 9001:2015 requirements – Clauses 8- 10
3.15 - 3.35 pm	Closing the gap between ISO 9001:2008 & 2015 & Incorporating the new requirements into your system
3.35 – 3.50 pm	Break
3.50 – 4.30 pm	Exercise on ISO 9001:2015 Standards
4.30 – 5.00 pm	Q & A Session
5.00 pm	End of Session

اَللَّهُمَّ افْتَحْ عَلَيْنا حِكْمَتَك وانْشُرْ عَلَيْنا مِنْ خَزَائِنِ رَحْمَتِك يَا أَرْهَمَ الرَّحْمِينْ

1. To **investigate** the general concept of ISO 9001 : 2015 Management System

2. To **prepare** documents based on the requirements of ISO 9001 :2015

3. To **establish** the effective QMS based on the ISO 9001:2015. (Manual Kualiti, Risk Register, SOP, Quality Policy, Quality Objective, Strategic Planning, Strategic Action, Evaluation and Improvement)

- First published in 1987, ISO 9001 has consistently been ISO's **most popular series of standards**.

- Geneva Switzerland

- Malaysia is a member of ISO

- In Malaysia – Department of Standards Malaysia

- ISO 9000 – Vocabulary and fundamentals (Terminologies)

- ISO 9001-Quality Management System

- ISO 9004- Managing for sustained success of an organization
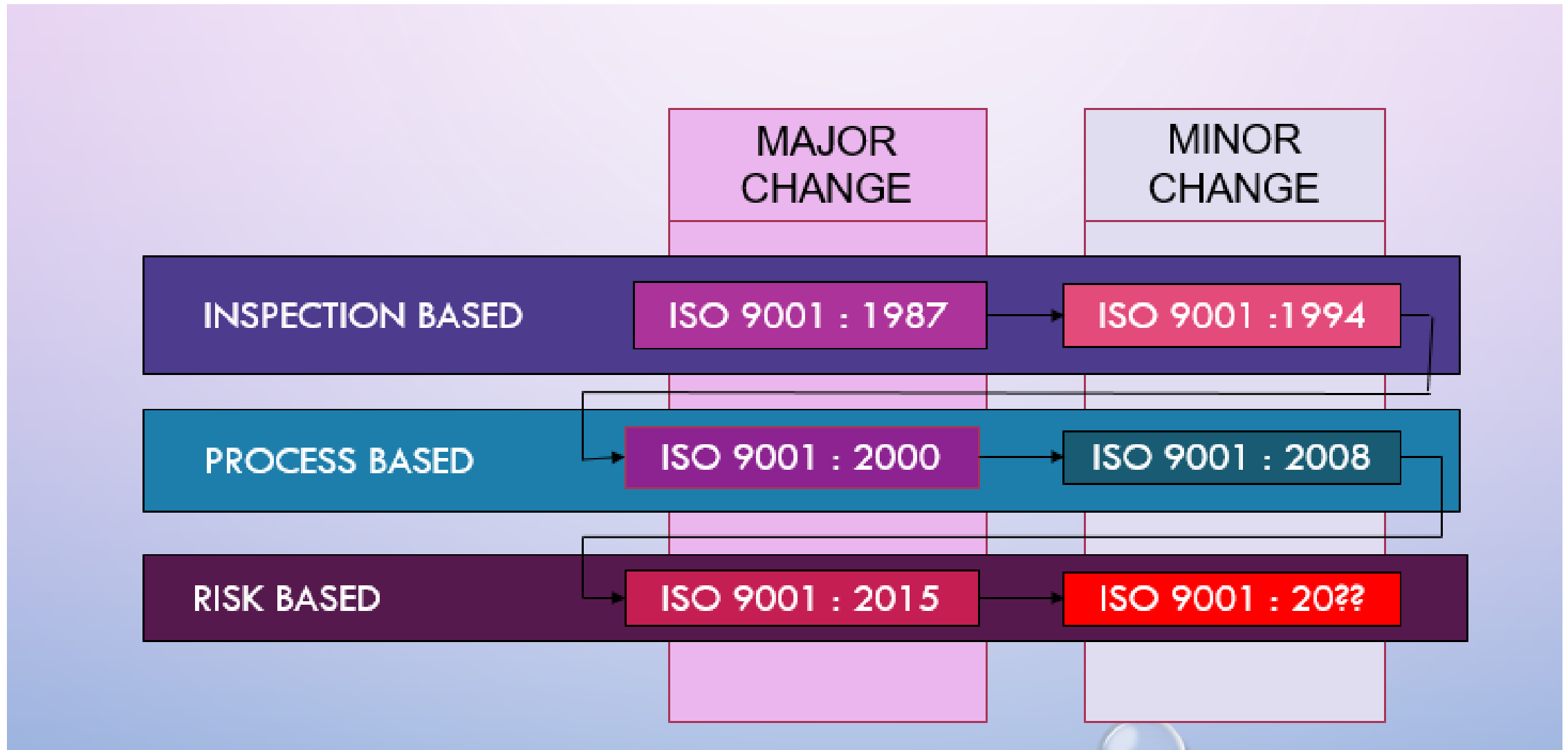
- There are several distinct stages when developing ISO standard; the key ones being :

  1. New work item proposal (NP)
  2. Working Draft (WD)
  3. Committee Drafts (CD)
  4. Draft International Standard (DIS)
  5. Final Draft International Standard (FDIS)
  6. International Standard (IS)

The standard is published after approval of the FDIS by participating national standards bodies.

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September 2015	→	ISO 9001:2015 published
Transition period	→	3 years

Both standards applicable

SEPT 2015	ISO 9001:2008 ISO 9001:2015 →	**AUG 2018**
SEPT 2018	And beyond →	ISO 9001:2015

*All certifications to
ISO 9001:2008 will
No longer be valid after September 2018*

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1. **Maintain relevance-** Improvement

2. Enhance an organization's ability to **satisfy customers.**

3. **Provide integrated approach** to organizational management and integrate with other management systems for example ISO 14001, ISO 18001etc.

4. Set a consistent foundation for the next 10 years.

5. Ensure the new standard **reflects the needs** of all potential user group.

1. **"Risk-Based thinking"** – Proactive Preventive Action
2. Increased requirement for Top Management Commitment.
3. Less emphasis on documents; Flexibility on documentation
4. Customer Satisfaction.
5. Process Approach.
6. A new common format has been developed for use in all management system standards (MSS). For example ISO 9001 and ISO 14001.
7. Enhance requirement for competent of resources.
8. Understand the context of the organization.
9. Organizational Knowledge.
10. Mentioned both products and services

- Introduction
  1. Scope
  2. Normative reference
  3. Terms and definitions
  4. Context of the organization (Plan)
  5. Leadership (Plan)
  6. Planning (Plan)
  7. Support (Do)
  8. Operation (Do)
  9. Performance evaluation (Check)
  10. Improvement (Action)

Comparison Between 2008 vs 2015

ISO 9001:2008

0. Introduction
1. Scope
2. Normative Reference
3. Terms and Definitions
4. Quality Management System
5. Management Responsibility
6. ---
7. Resource Management
8. Product Realization
9. Measurement, Analysis, and Improvement
10. ---

ISO 9001:2015

0. Introduction
1. Scope
2. Normative Reference
3. Terms and Definitions
4. Context of the Organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement
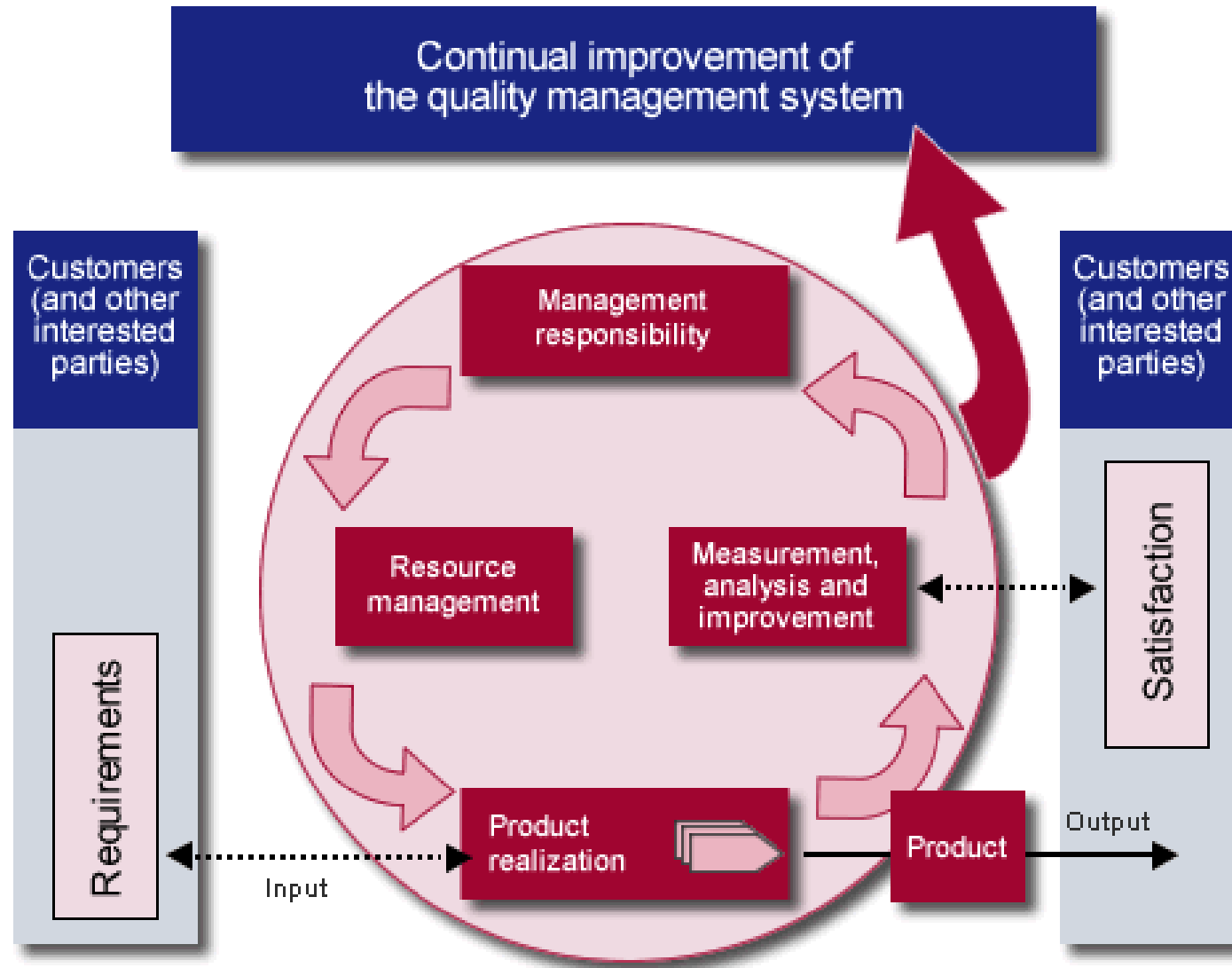
Figure 1. ISO 9001:2008 process model

ISO 9001 : 2015 NEW PROCESS MODEL
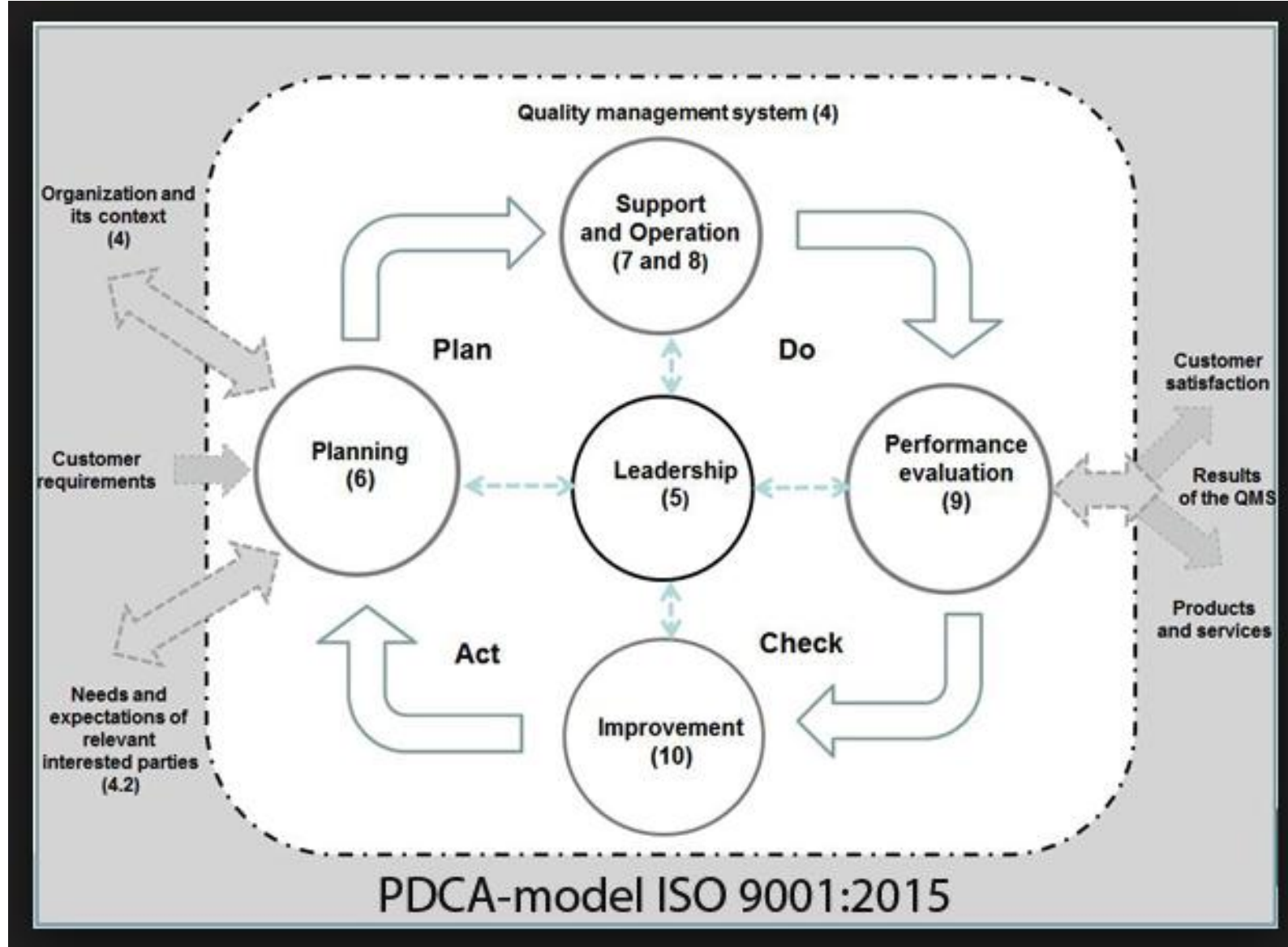
PDCA-model ISO 9001:2015

8 QMPs (2008)	7 QMPs (2015)
QMP 1 : Customer Focus	QMP 1 : Customer Focus
QMP 2 : Leadership	QMP 2 : Leadership
QMP 3 : Employee Involvement	QMP 3 : Engagement of People
QMP 4 : Process Approach	QMP 4 : Process Approach
QMP 5 : System Approach	QMP 5 : Improvement
QMP 6 : Continual Improvement	QMP 6 : Evidence-based Decision Making
QMP 7 : Factual-based Decision Making	QMP 7 : Relationship Management
QMP 8 : Win-win Relationship with Suppliers	

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used ➔ Application
Documentation, Records	Documented information
Work Environment	Environment for operation of processes
Purchased Product	Externally provided products and services
Supplier	External provider

1. **Scope**

2. **Normative reference**

3. **Terms and definition**

4. **Context of the organization**

       4.1   Understanding the organization and its context
       4.2   Understanding the needs and expectations of interested parties
       4.3   Determining the scope of QMS
       4.4   Quality management system and its processes

5. **Leadership**

       5.1   Leadership and commitment
       5.2   Quality Policies
       5.3   Organizational roles, responsibilities and authorities

6. **Planning for the QMS**

       6.1   Actions to address risks and opportunities
       6.2   Quality objectives and planning to achieve them
       6.3   Planning of changes

7. Support

7.1 Resources

    7.2 Competence
    7.3 Awareness
    7.4 Communication
    7.5 Documented Information

8. Operation

    8.1 Operational planning and control
    8.2 Determination of requirement for products and services
    8.3 Design and development of products and services
    8.4 Control of externally provided products and services
    8.5 Production and services provision
    8.6 Release of products and services
    8.7 Control of non conforming process outputs, products and services

9.   Performance evaluation

9.1   Monitoring, measurement, analysis, and evaluation

9.2   Internal audit

9.3   Management review

10. Improvement

10.1   General

10.2   Non-Conformity and corrective action

10.3   Continual improvement

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Context of the organization

4.1 CONTEXT OF THE ORGANIZATION

4.1
Understanding the organization and its context

4.2
Understanding the needs and expectations of interested parties

4.3
Determining the scope of the quality management system

4.4
Quality management system and its processes

The organization **shall**:

- Determine **internal and external issues** that are relevant to its purpose and its strategic direction (Hala Tuju Strategik).

- Monitor (memantau) and review (mengkaji semula) information relating to internal and external issues.
  - i. Use SWOT Analysis
  - ii. Internal and external
  - iii. Positive and negative

Evidence : Strategic Planning, Workshop & Presentation, Training Program, Minute of Meeting etc.

	HELPFUL (for your objective)	HARMFUL (for your objective)
INTERNAL (within organisation)	**Strengths** • ____ Budget/Finance • ____ Infrastructure • ____ Technology • ____ Manpower – Competency • ____ Team Work Culture Working Environment Communication	**Weaknesses** • ____ Budget/Finance • ____ Infrastructure • ____ Technology • ____ Manpower – Competency • ____ Team Work Culture Working Environment Communication
EXTERNAL (outside organisation)	**Opportunities** • ____ New Technology • ____ New Government Policy • ____ Social Patterns • ____ Population Profile • ____ Location • ____ Local Activities	**Threats** • ____ • ____ New Legislation • ____ Economy Crisis • ____ Contractors • ____ Supplier

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To consistently provide products and services that meet customer and statutory (Perundangan) and regulatory (Peraturan) requirements, the organization shall :-

a) determine the interested parties **(Customer + Stakeholders)** that have relevant to the quality management system.

b) determine the requirement of these interested parties that are relevant to the QMS.

Monitor and review the information about these interested parties

Evidence: Feedbacks, Minutes of Meeting, Policies etc.

In determining the scope of the QMS, the organization shall determine the boundaries and applicability of the QMS to establish the scope. It shall consider :

  a) External and internal issues (referred to in 4.1)
  b) Relevant requirements of interested parties (referred to in 4.2)
  c) Its products and services (Main activities)

  Shall be available and be maintained as documented information.

The scope shall be available stating the :
  • Product and services covered by the QMS
  • Justification where the requirement cannot be applied

Evidence: Manual Quality, Objective Quality, Strategic Planning Etc.

The new standard further promotes the **process approach** beyond the existing requirements in ISO 9001:2008.

The organization shall determine the process needed for the QMS and shall determine :

a) The inputs and outputs of the processes
b) The sequence and interaction of these processes
c) The criteria, methods, including measurements and related performance indicators
d) The resources needed
e) The assign of the responsibilities and authorities
f) The risks and opportunities (Clause 6.1)
g) Evaluate these processes and implement any changes to achieve intended results.
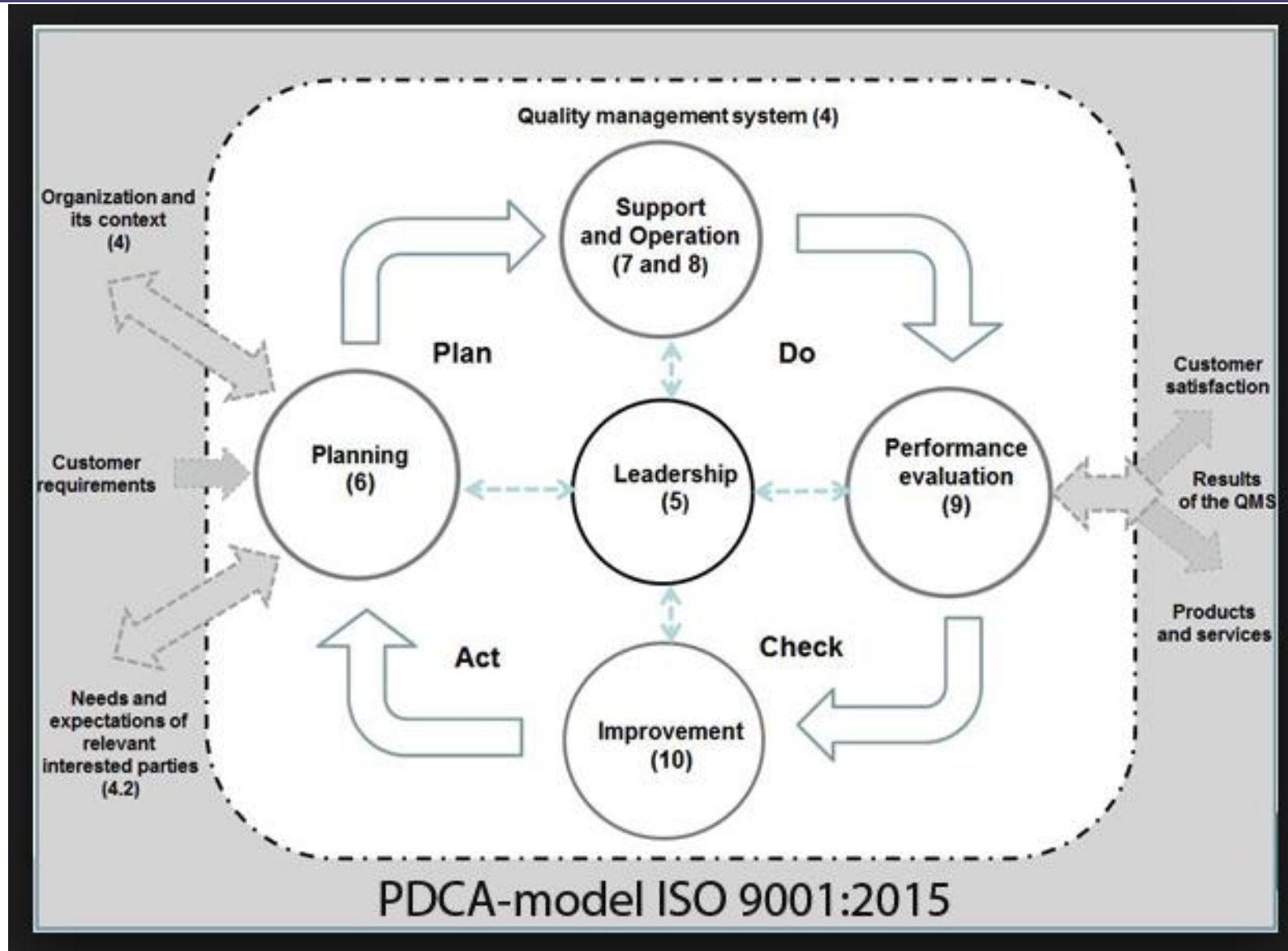h) Improve the processes and the QMS
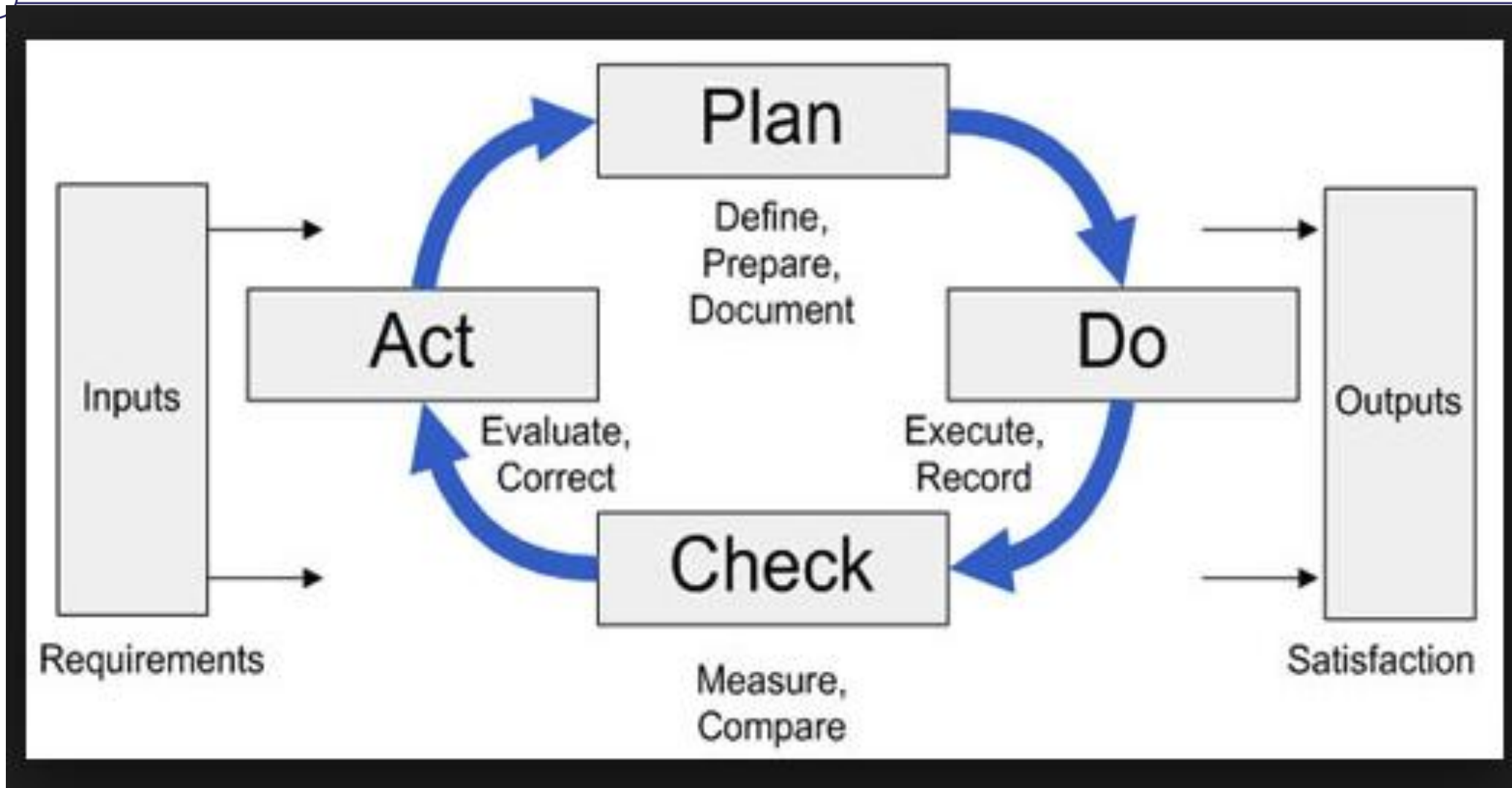
Evidences: Vision, Mission, Strategic Planning, Management Meeting, CQI report, Research Policy etc.

5. LEADERSHIP

5.1
Leadership and commitment

5.2
Policy

5.3
Organizational roles, responsibilities and authorities

PDCA-model ISO 9001:2015

Shall demonstrate leadership and commitment through :

- Accountable for QMS effectiveness
- Ensure Quality policy & objectives compatible with strategic direction
- Integrate QMS requirements into core business process
- Provide resources
- Communicate

- Ensure achieve intended outcomes
- Direct and support other persons
- Promote continual improvement
- Support other relevant management roles to demonstrate their leadership

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that :

a) **Customer requirements** and applicable statutory and regulatory requirements are determined and met

b) The risks and opportunities that can affect conformity of products and services are **determined and addressed.**

c) The focus on enhancing customer satisfaction is **maintained.**

Evidences: Feedbacks, CQI Report, Minutes of Meeting, Quality Objectives, etc.

5.2.1   Top management shall establish a **Quality policy** that :

a) Is appropriate to the purpose and context of the organization
b) Provides a framework for setting the **quality objectives**
c) Includes a commitment to satisfy applicable requirements
d) Includes a commitment to continual improvement of QMS

5.2.2   Communicating The Quality Policy :
          The Quality Policy Shall:

a) **Be available** and be maintained as documented information
b) **Be communicated**, understood and applied within the organization
c) **Be available to relevant interested parties as appropriate**

Evidences: Quality Policy, Quality Objectives, Minutes of Meeting, Strategic Planning,etc.

- Top management shall ensure that the responsibilities and authorities for relevant roles are **assigned and communicated** within the organization.

- Top management **shall assign** the responsibility (Tanggungjawab) and authority (kuasa) for :

  a) Ensuring that QMS conforms (Patuh) to the requirements
  b) Ensuring the processes are delivering their **intended outputs** (KPI)
  c) Reporting the performance of QMS and on opportunities for improvement
  d) Ensuring the **promotion of customer focus**
  e) Ensuring the **integrity of QMS is maintained** when changes to the QMS are planned and implemented. (Dokumen yang lengkap dan Jelas)

Evidences: Job scope, List of Committee, Appointment letter, Strategic Planning, etc.

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6. PLANNING

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes

- 6.1.1 When planning of QMS, shall consider the issues referred to in 4.1 and 4.2 and determine the risks and opportunities that need to be addressed to :
    a) Ensure the QMS can achieve its intended outcome
    b) Enhance desirable effects.
    c) Prevent or reduce undesired effects
    d) Achieve continual improvement

- 6.1.2 The organization shall plan :
    a) Action to address **(menangani)** these risks and opportunities
    b) How to integrate and implement the action into QMS processes
    c) Evaluate the effectiveness of these actions – Penilaian Keberkesanan

Evidences: Risk Management, CQI Report, Operational Excellence, Management Meeting, Strategic Planning etc.

Risk Assessment Format - Sample

Process/ Location	Dept.	Prepared by: Date:	Checked by: Date:	Approved by: Date:
		Review Date:	1	2

1. Risk Identification			2. Risk Assessment				3. Risk Control	
Process	Risk	Effect	Current Risk Control	Probability	Severity	Risk	Recommended Action/ Additional Control	PIC (Due Date/ Status)

6.2.1 The organization shall establish **Quality objectives** at relevant functions, levels and processes.

The Quality objectives shall :

  a) Be consistent with Quality policy
  b) Be measurable
  c) Take into account applicable requirements
  d) Be relevant to conformity of products and services and enhancement of customer satisfaction
  e) Be monitored
  f) Be communicated
  g) Be updated as appropriate

Evidences: Quality Objectives, CQI Report, Minutes of Meeting, Website, Customer feedbacks, etc.

6.2.2 When planning how **to achieve its Quality Objectives**, the organization shall determine :

a) What will be done – Apa yang perlu dilakukan?

b) What resources will be required – Sumber yang diperlukan?

c) Who will be responsible – PIC?

d) When it will be completed – Tarikh siap?

e) How the results will be evaluated – Proses Pengukuran?

Where the need of change to the quality management system is determined, the change shall be carried out in a planned manner (see 4.4). Shall consider :

a) The purpose of the change and any potential consequences – **Tujuan dan Potensi.**

b) The integrity of the quality management system

c) The availability of resources – **Keberadaan Sumber.**

d) The allocation or reallocation of responsibilities and authorities – **Agihan Semula/ Perubahan Struktur.**

Establish procedure to control/smooth/consistent the process.

Evidences: Minutes of meeting, Risk Management, Job Scope, Workshop etc.

7. SUPPORT

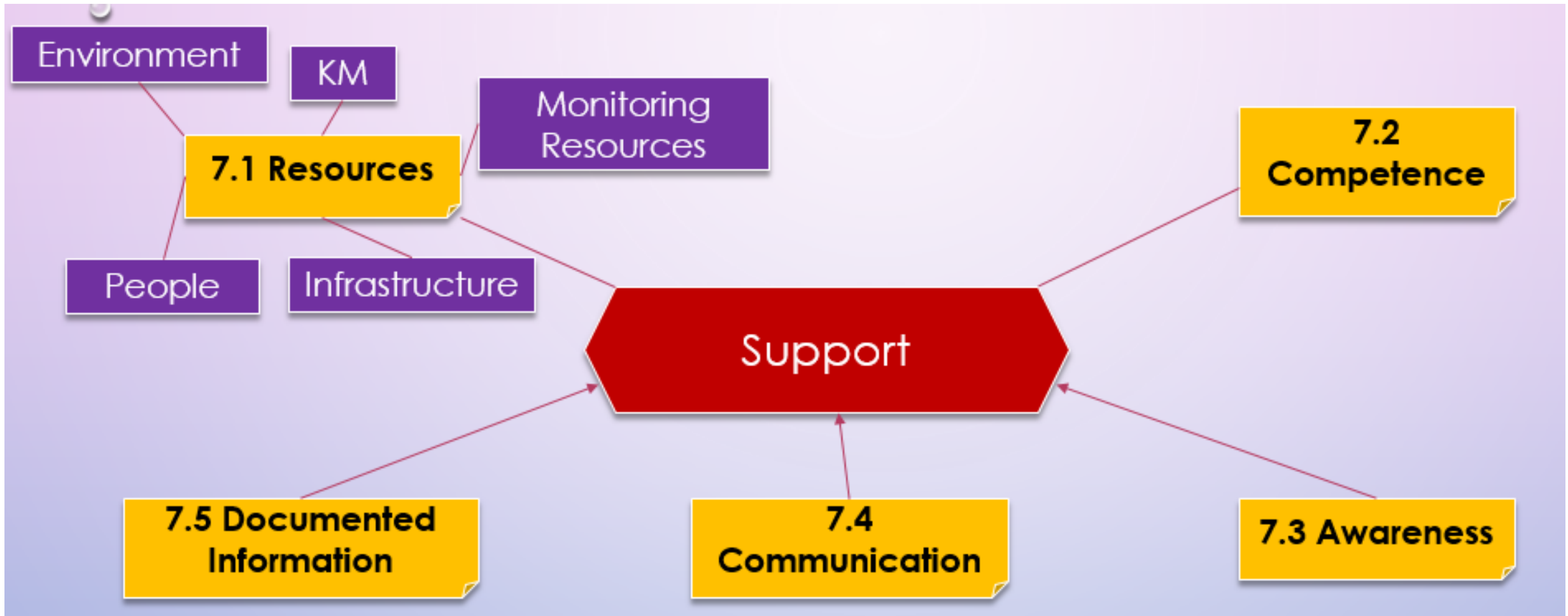**7.1** Resources

Competence **7.2**

7.3 Awareness

Communication **7.4**

7.5 Documented Information

- The organization **shall determine** and **provide** the resources needed for establishment, implementation, maintenance and continual improvement of the QMS. Resources considerations include:

  a) Capability of and constraints (Kekangan) in existing internal resources,
  b) What needs to be obtained from external providers.

Evidences: Organization Chart, Job Scope, Customer Feedbacks,etc.

Organization **shall determine** and **provide persons** necessary for the effective implementation of the QMS and for the operation and control of its processes. **(Operasi dan kawalan proses)**

Evidences: Job Scope, Appointment Letter, Organization Chart, Minutes of Meeting, etc.

The organization shall **determine, provide and maintain** the infrastructure necessary for the operation of its processes and to achieve conformity of products and services :

For Example:
   Building , Equipment, Instruments, Software, Transport, Computers etc.

The organization **shall determine, provide and maintain** the environment necessary for the operation.

- Can include physical, social, psychological, environment and other factors such as temperature, humidity, ergonomic and cleanliness.

Keperluan Tempat Kerja ; Meja, Kerusi, Komputer dll.

The organization shall:

• Determine resources needed to ensure valid and reliable monitoring and measuring results.

• Ensure the resources provided :

    a) Are suitable for the specific type of monitoring and measurement activities

    b) Maintained to ensure their continuing fitness for their purpose

• Retain appropriate documented information of fitness for purpose of monitoring and measuring resources.

(Simpan rekod Calibration)

When **measurement traceability is a requirement**, or is considered by the organization to be an essential part of providing confidence on the validity of measurement results, measurement equipment shall be :

a) Calibrated or verified, or both at specified intervals or prior to use, against measurement standard traceable to international or national measurement standard; when no such standards exist the basis used for calibration or **verification shall be retained as documented information;**

b) **Identified in order to determine their status**

c) Safeguarded from adjustments, damage or deterioration

Shall take appropriate action as necessary if measuring equipment is found to be unfit.

- Organization shall **determine, maintain, and make available** knowledge needed for operation of its processes and to achieve conformity of products and services.

- Need also to consider whether additional knowledge needed to address changing needs and trends.

- **Internal Sources**: Regular meeting, presentation, results of improvement etc.

- **External sources** : Standard, conferences, gathering knowledge from customer or external provider

The organization shall:

a) Determine the necessary **competence of person (s)** doing work under its control that affects its QMS performance.

b) Ensure these persons are competent on the basis of appropriate education, training or experience. – Sijil Kelayakan.

c) Take action **to acquire the necessary competence** and evaluate the effectiveness – Feedbacks, CQI Report, Propens.

d) Retain (Rekod) appropriate documented information as evidence of competence. Fail Peribadi.

The persons doing work under the organization's control shall have awareness on:

a) The quality policy; University, Faculty, etc.
b) The relevant quality objective: University, Faculty, etc.
c) Their contribution to the effectiveness of QMS
d) The implication of not conforming with QMS requirements (Non- Conformity and Conformity)

Evidences: Website, Notice Board, Workshop, Briefing etc.

- Includes internal and external Communication relevant to QMS
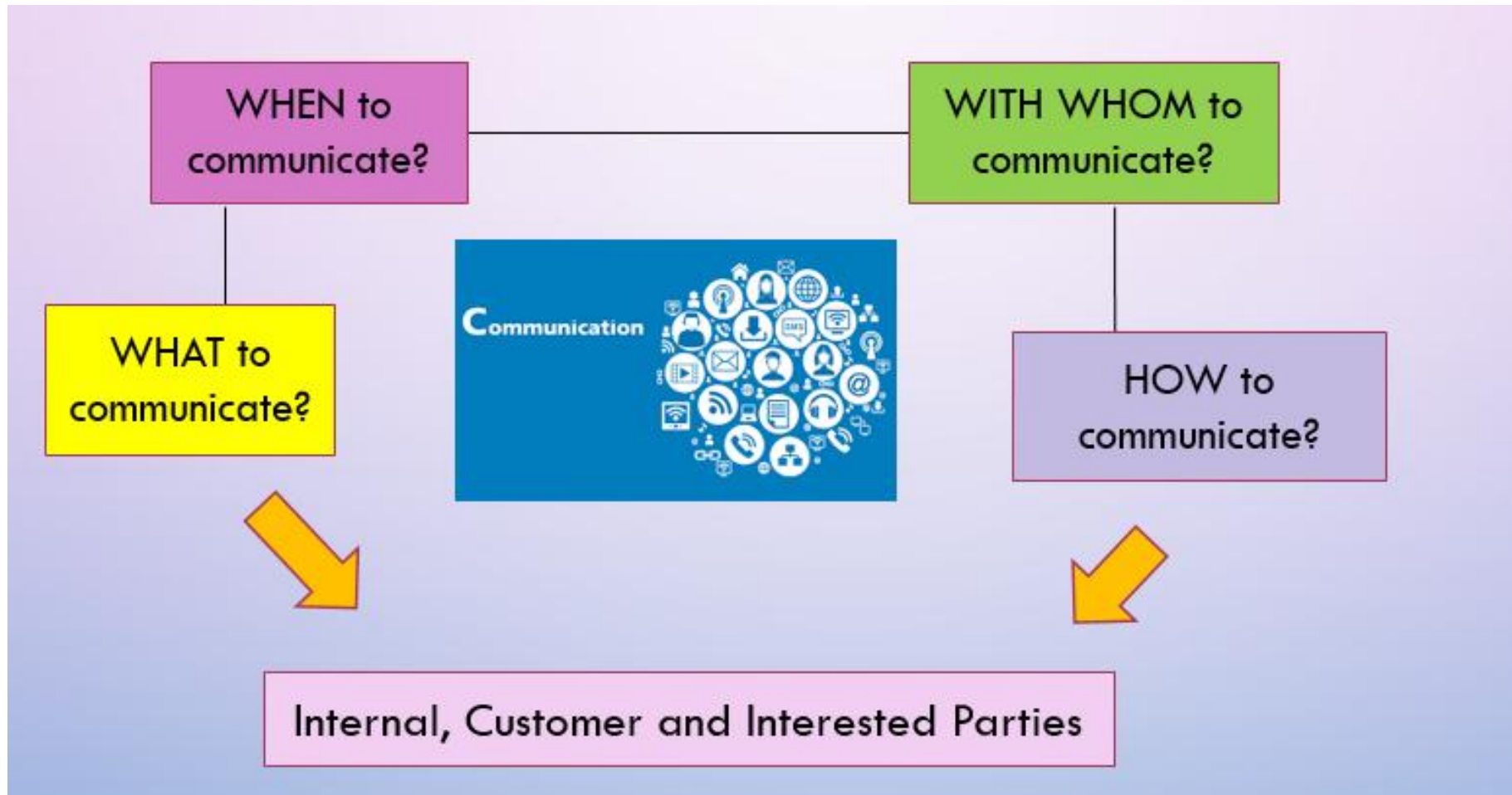
Evidences: Meeting, Website, Notice Board, Workshop, Briefing, Poster, Banner, etc.

- More flexible in documentation

Document		
Record		

Document / Record → 2008 version → Documented information

- Retain documented information as evidence of …..' i.e. records
- Maintain documented information' to mean documentation other than records

Note : *The extent of documented information for a quality management system can differ from organization to another*

7.5.2 Creating & Updating

↓

7.5.3 Control

Identification & description (e.g title, date, author, reference number)

Format (e.g. language, software version, graphics, media)

Review and approval

Ensure available and suitable for use

Ensure adequate protection

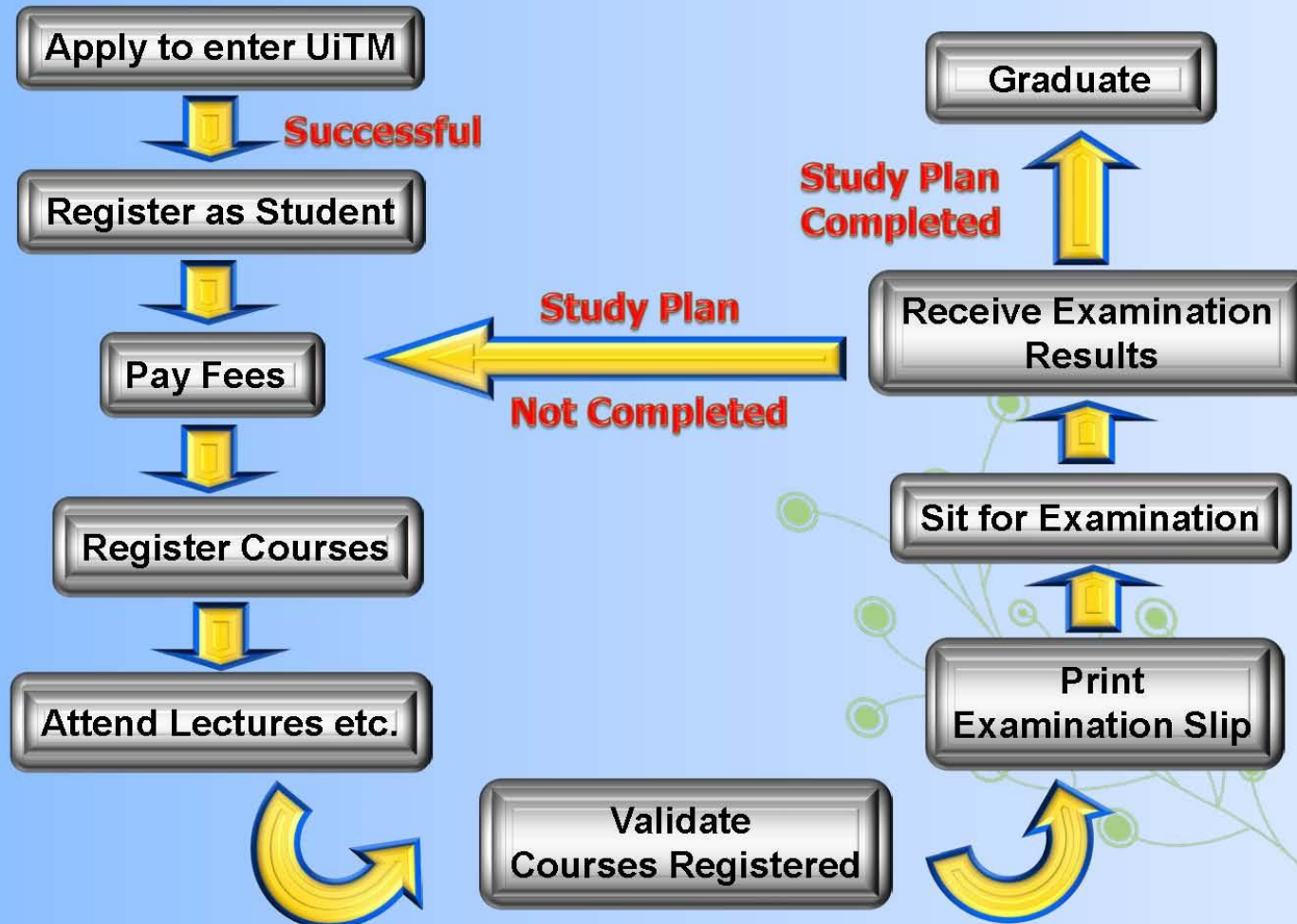| Distribution access, retrieval, use | Storage, preservation, legibility | Version Control | Retention & disposition |

Includes documented information of external origin

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8. OPERATION

8.1 Operational planning and control

8.2 Requirements for products and services

8.3 Design and development of products and services

8.4 Control of externally provided processes, products and services

8.5 Production and service provision

8.6 Release of products and services

8.7 Control of nonconforming outputs

The organization **shall plan, implement and control** the processes **as outlined in 4.4**, needed to meet requirements for the provision of products and services and **to implement the actions determined in 6.1** by :

a) Determining requirements for the product and services
b) Establishing criteria for the processes and for the acceptance of products/services
c) Determining the resources needed (Sumber yang diperlukan)
d) Implementing control (Laksanakan Kawalan terhadap proses)
e) Determining, maintaining and retaining documented information.

Evidences: Strategic Planning, Objective Policy, Objective Quality, Risk Register, etc.

The organization shall **establish, implement and maintain a process to determine** the requirements for the products and services to be offered to potential customer.

Shall ensure :

a) Product and service requirements and applicable statutory and regulatory requirements are defined;

b) It has the ability to meet the defined requirements and substantiate the claims for the products and services it offers

Evidences: Contract Agreement, Website, Profile, Feedbacks from industries, Market Surveys (Employer & Alumni), Curriculum Review Procedure Etc.
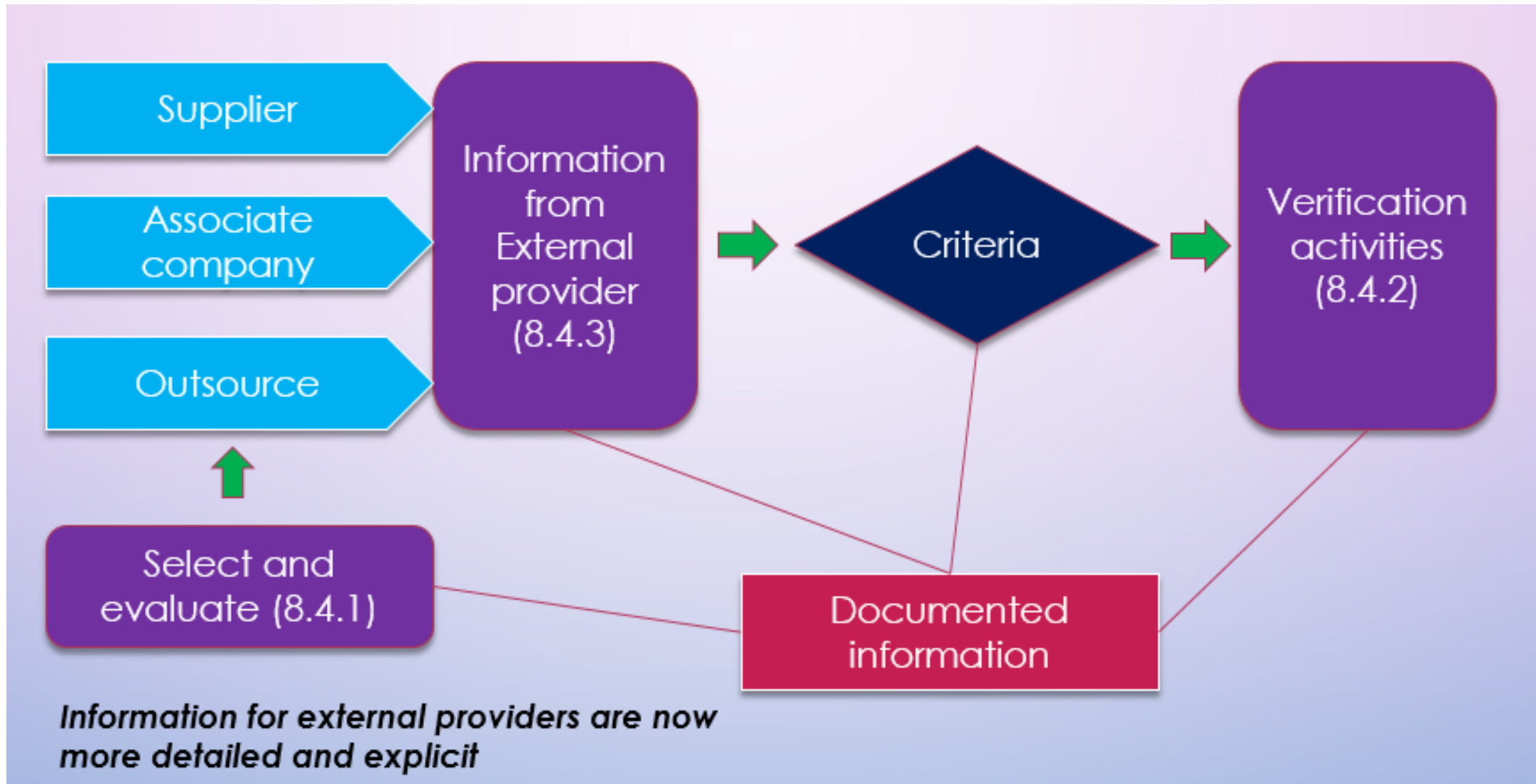
The organization shall review: (Engagement with Customer)

a) Requirements specified by the customer, including the requirements for delivery and post delivery activities

b) Requirements not stated by the customer but necessary for specified or intended use, when known;

c) Requirements specified by the organization

d) Statutory and regulatory requirements related to the product and service

e) Contract or order requirements differing from those previously expressed

Evidences: Minutes of Meeting, Customer Feedbacks, Policy, Guidelines, Etc.

The organization shall:

✓Establish, implement and maintain an appropriate D&D process (clause 8.3.1)

✓Clarification of the application of D&D requirements (clause 8.3.1)

✓D&D planning (clause 8.3.2)

✓D&D inputs (clause 8.3.3)

✓D&D controls – new clause combinig reviews, verification & validation (clause 8.3.4)

✓D&D outputs (clause 8.3.5)

✓D&D changes (clause 8.3.6)

Evidences: Curriculum Review Procedure, New Program, Guidelines, policy, Etc.

Supplier → Information from External provider (8.4.3)

Associate company →

Outsource →

Select and evaluate (8.4.1)

Criteria

Verification activities (8.4.2)

Documented information

Information for external providers are now more detailed and explicit

Shall plan and carry out production controlled conditions. Controlled conditions shall include, as applicable :

a) Availability of documented information that defines characteristics of products and services

b) Availability of documented information that defines the **activities to be performed and results to be achieved**

c) The availability and use of **suitable monitoring and measuring resources**

d) Monitoring and measurement activities at **appropriate stages and acceptance criteria** have been met

e) The use and control of suitable infrastructure and process environment

f) **The competence of person**

g) **Validation** where resulting output cannot be verified

h) The implementation of **actions to prevent human error**

i) The implementation of **products and services release** and delivery and post-delivery activities

Evidences: Staff Qualification, Experience, Training Activities, List of Equipment, Certification, Organization Charts, Job Scope, Etc.

- Where necessary to ensure conformity of products and services, the organization shall use suitable means to identify process outputs.

- Shall identify the status of process outputs with respect to monitoring and measurement requirements

- Where traceability is a requirement, shall control the unique identification of the process output and retain any documented information necessary to maintain traceability.

Evidences: Student ID, No Permohonan, No Tender , Kod Program, Kod Kampus etc.

- Used to be "customer property"

- Intent still the same, e.g.. to take care of customer's property while it is under the organization's control or being used by the organization.

- Requirement extended to cover not just customer property but also property **belonging to external providers**.

- Can include materials, components, tools, customer premises, **intellectual property and personal data.**

Evidences: Policy, Guidelines, Procedure, Minutes of Meeting, etc.

- Shall ensure preservation of process outputs during production and services provision, to the extent necessary to **maintain conformity to the requirements.**

- Can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection

Evidences: Transcript, Scroll, etc.

- Shall meet requirements for the post delivery activities associated with the products and services

- In determining the extent of post-delivery activities that are required, the organization shall consider :

  a) Statutory and regulatory requirements
  b) The potential undesired consequences associated with its products and services
  c) The nature, use and intended lifetime of the products and services
  d) Customer requirements
  e) Customer feedback

- The organization shall **review and control changes** for production or service provision to the extent necessary to ensure continuing conformity with requirements.

(Semakan Kurikulum)

- The organization **shall retain documented information** describing the results of the review of changes, the personnel authorizing the change, and any necessary actions arising from the review.

Evidences: (Surat JAF, JKIKU, Senat, Tender Drawing, Construction Drawing, Minutes of Meeting, etc.)

- The organization shall implement planned arrangements at **appropriate stages to verify** that product and service requirements have been met.

- The release of products and services to the customer shall not proceed until planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority, and as applicable, by the customer. Documented information shall provide evidence of conformity with acceptance criteria and traceability to the **person authorizing the release**.

(Keputusan peperiksaan, Surat Konvo, Program Baru, Etc.)

- 8.7.1 The organization **shall deal with nonconforming outputs** in one or more of the following ways :
  a) **Correction**
  b) Segregation, containment, return or suspension of provision of products and services
  c) **Informing the customer**
  d) Obtaining authorization for acceptance under concession

- 8.7.2 The organization shall retain documented information that :
  a) Describes the **nonconformity**
  b) Describes the **actions taken**
  c) Describes any concessions obtained;
  d) Identifies the authority deciding the action in respect of nonconformity

9. PERFORMANCE EVALUATION

9.1

Monitoring, measurement, analysis and evaluation

9.2

Internal Audit

9.3

Management review

9.1.1 **General**

The organization shall determine:

- a) **What needs** to be monitored and measured
- b) **The methods** for monitoring, measurement, analysis and evaluation as applicable – Valid Results
- c) **When** the monitoring and measuring shall be performed
- d) When the results from the monitoring and measurement shall be **analyzed and evaluated**.

- Shall evaluate the performance and the **effectiveness of the QMS**

- Shall retain appropriate documented information as evidence of the results.

- The organization shall **monitor customers' perceptions** of the degree to which their needs and expectations have been met.
- Shall determine the methods for **obtaining, monitoring and reviewing** this info.

Can include customer satisfaction/opinion surveys, customer feedback on delivered products and services, market share analysis, compliments, warranty claims and dealer reports.

Evidences: Minutes of meeting, Feedbacks, Seminar, Etc.

1. The organization shall **analyze and evaluate** appropriate data and information arising from monitoring and measurement.

2. The result of analysis shall be used to evaluate :
   a) Conformity of products and services
   b) The degree of customer satisfaction
   c) The performance and effectiveness of the QMS
   d) If planning has been implemented effectively
   e) The effectiveness of actions taken to address risks and opportunities
   f) The performance of external providers
   g) The need for improvements to the QMS

**Evidences: Exam results, CGPA, AD, ANC, Feedbacks etc.**

The organization shall conduct Internal Audit at planned intervals to ensure that the organization's requirements and the requirements of this standard, are met and the QMS is effectively implemented and maintained.

The organization shall:

a) Plan, establish, implement and maintain an audit programme (s) including the frequency, methods, responsibilities, planning requirements and reporting which shall take into consideration the importance of the processes concerned, changes affecting the organization, and results of previous audits.

b) Define audit criteria and scope

c) **Select auditors** and conduct audits objectively and impartially (Certification, Audit Plan,

d) Ensure results of audit are reported to relevant management

e) Take appropriate correction and corrective actions

f) **Retain documented information**

Evidences: Results of Audit, Auditors with qualification, Audit Schedule, Audit Plan, etc.

Audit Program

Methods

Frequency

Responsibilities

Planning requirements

Reporting

Internal Audit

Retain documented information

Correction and Corrective action

Reported to relevant management
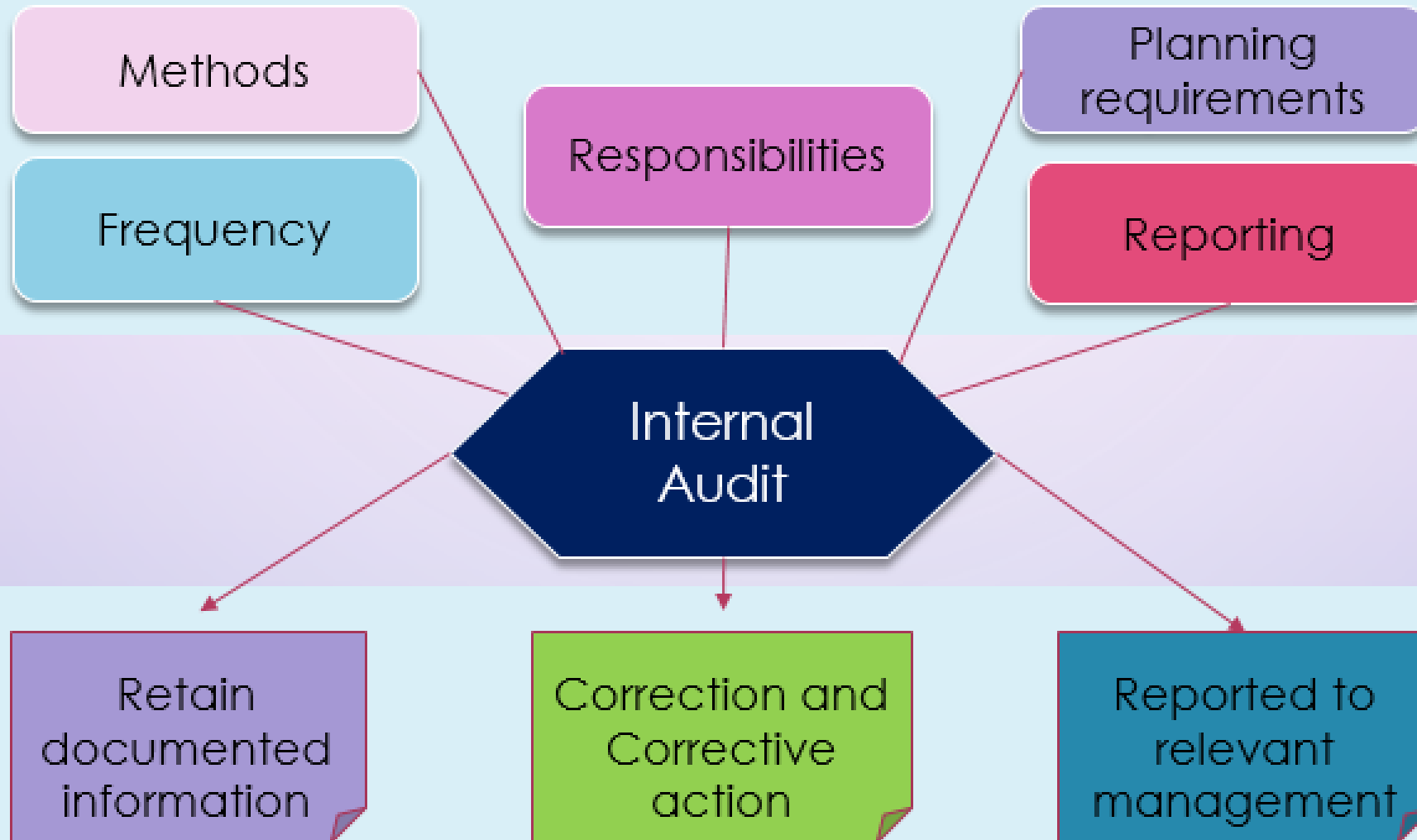
Top management shall take into consideration :

a) The status of actions from previous management reviews

b) **Changes in external and internal issues** that are relevant to QMS

c) Information on quality performance which includes:

  1. Customer satisfaction & feedback from relevant interested parties
  2. The extent to which quality objectives have been met
  3. Process performance and conformity of products and services
  4. Nonconformities and corrective actions
  5. Monitoring and measurement results
  6. Audit results
  7. Performance of external providers

d) Adequacy of resources

e) The effectiveness of actions taken to address risks & opportunities

f) Opportunities for improvement

Evidences: Minutes of Meeting, Customer Feedbacks, Risk Register etc.

The output of the management review shall include decisions (Keputusan) and actions (Tindakan) related to:

a) Opportunities for improvement

b) Any need for changes to the quality management system

c) Resource needs

The organization shall retain documented information as evidence of the results of management reviews.

Evidences: Minutes of meeting, Meeting Schedule, Examiner Report, Industry Meeting, Etc.

10. IMPROVEMENT

10.1 General

Nonconformity and corrective action **10.2**

10.3 Continual improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) Improving products and services to meet requirements and address future needs and expectations

b) Correcting, preventing or reducing undesired effects

c) Improving the performance and effectiveness of QMS

Note : *Improvement can include correction (reactive action), corrective action, continual improvement (incremental), breakthrough change (radical), innovation (creative) or by re-organizing (transformation)*

When a nonconformity (also complaint) occurs, the organization shall :

a) React to the nonconformity, and as applicable:
   1) Take action to control and correct it
   2) Deal with the consequences

b) Evaluate the need for action to eliminate the causes by :
   1) Reviewing & analyzing the nonconformity
   2) Determining the causes of nonconformity
   3) Determining if similar nonconformities exist, or could potentially occur

c) Implement action needed

d) Review the effectiveness of corrective action taken

e) Update risks & opportunities

f) Make changes to the QMS

The organization shall:

- Continually improve the suitability, adequacy and effectiveness of the QMS

- Shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs/opportunities that shall be addressed as part of continual improvement.

❑*Where applicable, shall select and utilize applicable tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.*

سُبْحَانَكَ اللَّهُمَّ وَبِحَمْدِكَ أَشْهَدُ أَنْ لاَ إِلهَ إِلاَّ أَنْتَ أَسْتَغْفِرُكَ وَأَتُوْبُ إِلَيْكَ

Artinya : Maha Suci Engkau ya Allah, dengan memuji-Mu aku bersaksi bahwa tiada tiada Tuhan melainkan Engkau, aku memohon pengampunan-Mu dan bertaubat kepada-Mu.

Thank You

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