



UNIVERSITI
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Institut
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Pengembangan
Ilmu

INSTITUT KUALITI DAN PENGEMBANGAN ILMU (InQKA)



UNIVERSITI
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Institut
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Pembangunan
Ilmu

ISO 9001:2015





Presented by:

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*Research Area: Internal combustion engines,
Alternative fuels, Fuel additives, Combustion
behavior, Engine performance and emissions.*

اللَّهُمَّ افْتَحْ عَلَيْنَا حِكْمَتَكَ وَاَنْشُرْ عَلَيْنَا

مِنْ خَزَائِنِ رَحْمَتِكَ يَا أَرْحَمَ الرَّحِمِينَ

COURSE OBJECTIVES

1. To **investigate** the general concept of ISO 9001 : 2015 Management System
1. To **prepare** documents based on the requirements of ISO 9001 :2015
1. 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)

DASAR KUALITI

- ✓ UiTM komited untuk menguruskan universiti secara profesional demi melahirkan graduan Bumiputera yang berdaya saing, global dan beretika serta sentiasa memenuhi keperluan pelanggan.
- ✓ UiTM sentiasa meningkatkan keberkesanan dan kecekapan pengurusan kualiti melalui penambahbaikan secara berterusan untuk menjadi sebuah universiti bertaraf dunia.

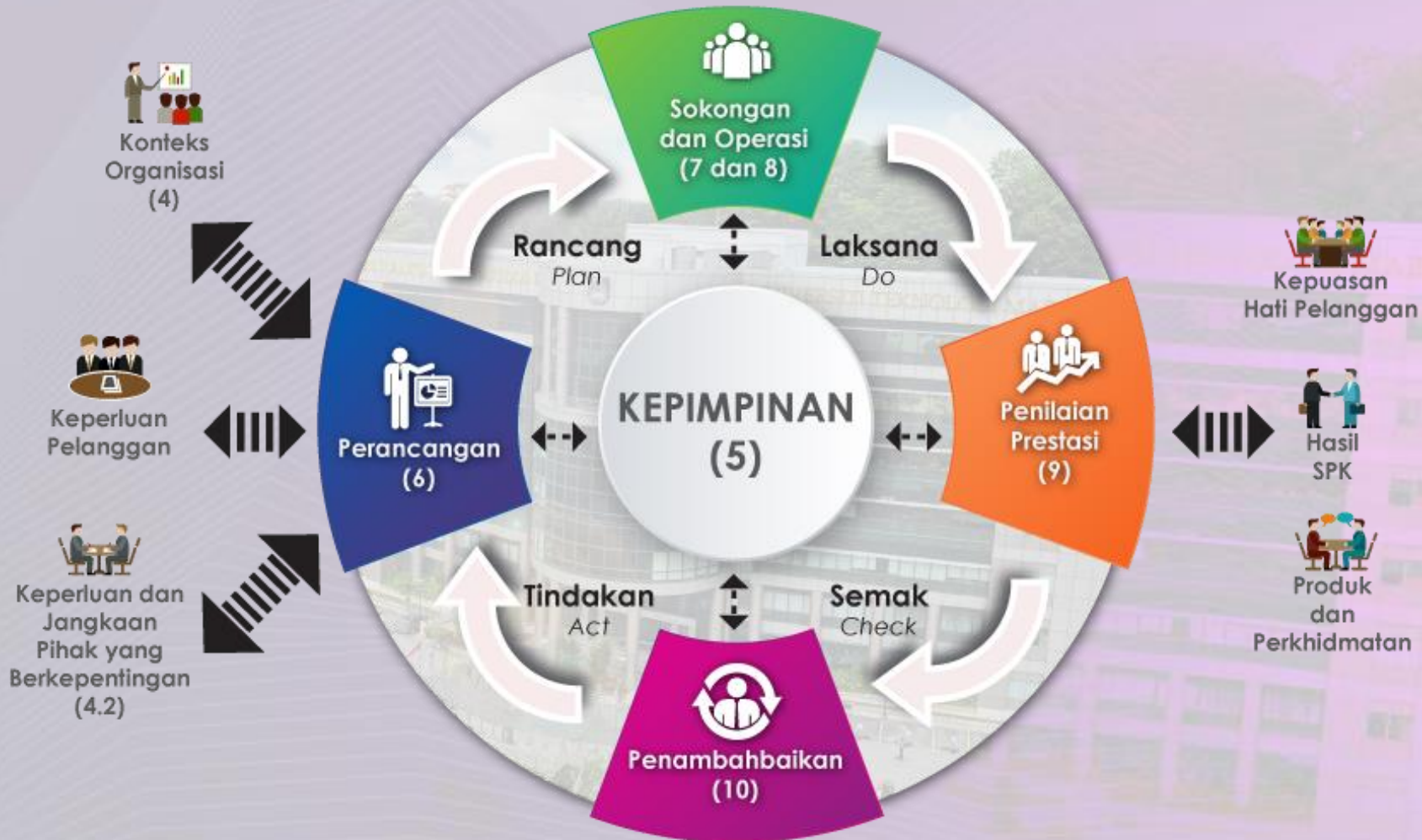
DOKUMEN KUALITI

Terdiri daripada:

- Manual Kualiti
- Prosedur Kualiti
- Dokumen Sokongan
 - ✓ Perancangan Strategik UiTM
 - ✓ Perancangan Strategik Jabatan
 - ✓ Lain-lain (rujuk Manual Kualiti ISO 9001:2015 Keluaran 02 Pindaan 01)

PELAN KUALITI: PENGURUSAN KORPORAT UiTM ISO 9001:2015

Sistem Pengurusan Kualiti (SPK) (Seksyen 4)



PDCA- Model ISO 9001:2015

Laporan Pencapaian Objektif Kualiti UiTM (Data Sehingga April 2019)

Objektif Kualiti	Sasaran	Pencapaian 2019
1. Mencapai enrolmen 200,000 pelajar (sepenuh masa dan asasi) menjelang 2020		
2. Memastikan semua kurikulum bersifat kerja kursus disemak setiap 4 tahun bagi program yang tempoh pengajiannya adalah 3 tahun atau kurang dan setiap 5 tahun bagi program yang tempoh pengajiannya 4 tahun		

Laporan Pencapaian Objektif Kualiti UiTM (Data Sehingga April 2019)

Objektif Kualiti	Sasaran	Pencapaian 2019
3. Memastikan sekurang-kurangnya 90% pelajar sepenuh masa pada peringkat Diploma dan Sarjana Muda bergraduat dalam tempoh yang ditetapkan (GOT)		
4. Memastikan sekurang-kurangnya 1,500 graduan PhD menjelang 2020		
5. Memastikan kadar kebolehpasaran siswazah melebihi 80% (Sarjana Muda) 95% (Diploma) dan Bekerja Sendiri: 3.5% tahun 2018 4.0% menjelang 2020		

Laporan Pencapaian Objektif Kualiti UiTM (Data Sehingga April 2019)

Objektif Kualiti	Sasaran	Pencapaian 2019
6. Memastikan bilangan penerbitan berindeks mencapai 50,000 menjelang 2020		
7. Memastikan nilai geran penyelidikan mencapai RM650 juta menjelang 2020		
8. Memastikan kecemerlangan dalam pemindahan ilmu dengan mengkomersilkan 8 produk hasil penyelidikan menjelang 2020		

BIL.	OBJEKTIF KUALITI	SASARAN	DATA SEMASA
1.	Mencapai enrolmen 200,000 pelajar menjelang 2025		
	a) Meningkatkan peratusan pelajar yang memperolehi 5A di peringkat SPM yang mendaftar bersama UiTM		

BIL.	OBJEKTIF KUALITI	SASARAN	DATA SEMASA
2.	Memastikan semua kurikulum melalui proses semakan sekurang-kurangnya sekali dalam tempoh 3 – 5 tahun		
	a) Peningkatan bilangan program yang mendapat pengiktirafan daripada badan-badan professional tempatan dan antarabangsa		

BIL.	OBJEKTIF KUALITI	SASARAN	DATA SEMASA
3.	Memastikan peningkatan peratusan pelajar bergraduan dalam tempoh yang ditetapkan (GOT) menjelang 2025 mengikut peringkat pengajian.		
	a) Peratusan graduan yang bergraduasi dengan CGPA 3.5 dan ke atas: <ul style="list-style-type: none">• Diploma• Sarjana Muda• Sarjana (Kerja Kursus)		

BIL.	CADANGAN OBJEKTIF KUALITI	SASARAN	DATA SEMASA
4.	a) Memastikan sekurang-kurangnya 3,000 graduan PhD menjelang 2025		
	b) Peratusan pelajar PhD dari luar negara yang bergraduat bersama UiTM		
5.	Memastikan kadar kebolehpasaran siswazah melebihi <ul style="list-style-type: none">• 80% (Sarjana Muda)• 95% (Diploma)• 5% bekerja sendiri		

BIL.	CADANGAN OBJEKTIF KUALITI	SASARAN	DATA SEMASA
6.	Memastikan bilangan penerbitan berindeks mencapai 50,000 menjelang 2025		
	a) Meningkatkan jumlah penerbitan berindeks Q1 menjelang 2025		
7.	Memastikan nilai geran penyelidikan mencapai RM 1 bilion menjelang 2025		

BIL.	CADANGAN OBJEKTIF KUALITI	SASARAN	DATA SEMASA
8.	Memastikan kecemerlangan dalam pemindahan ilmu dengan mengkomersilkan 50 produk hasil penyelidikan menjelang 2025		
	a) Memastikan kecemerlangan dalam pemindahan ilmu melalui pengkomersilan produk hasil penyelidikan dan perundingan kepakaran dengan jumlah nilai RM10 juta menjelang 2025		
9.	Meningkatkan peratusan pensyarah (sedia ada dan pengambilan baru) dengan PhD		

PEMETAAN OBJEKTIF KUALITI UiTM TERHADAP TERAS STRATEGIK UiTM

TERAS STRATEGIK UiTM

STRATEGIK SOKONGAN

- Pendidikan 5.0@UiTM
- Graduan seimbang dan berciri keusahawanan
- Perluasan Akses

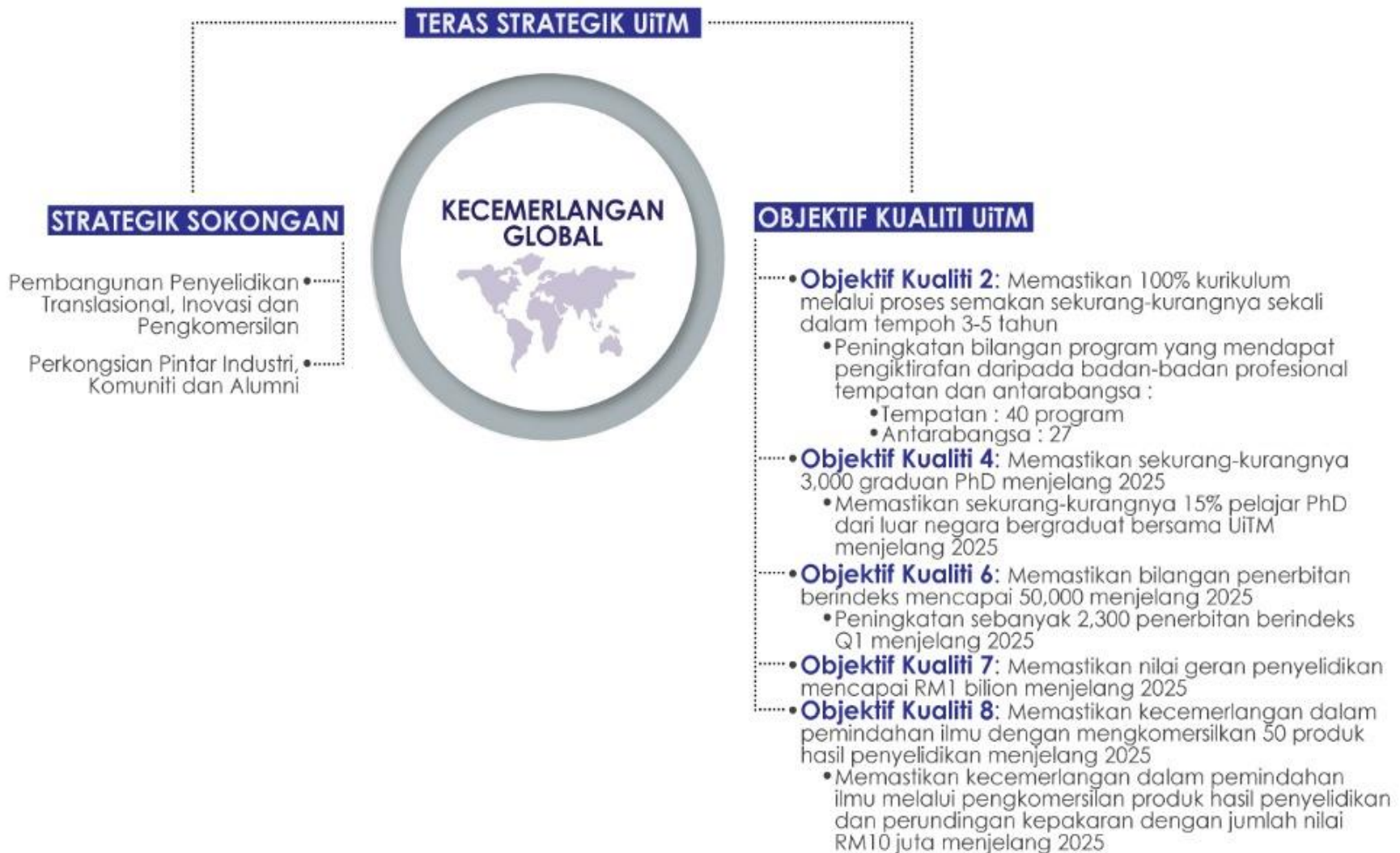


PENDIDIKAN BERKUALITI

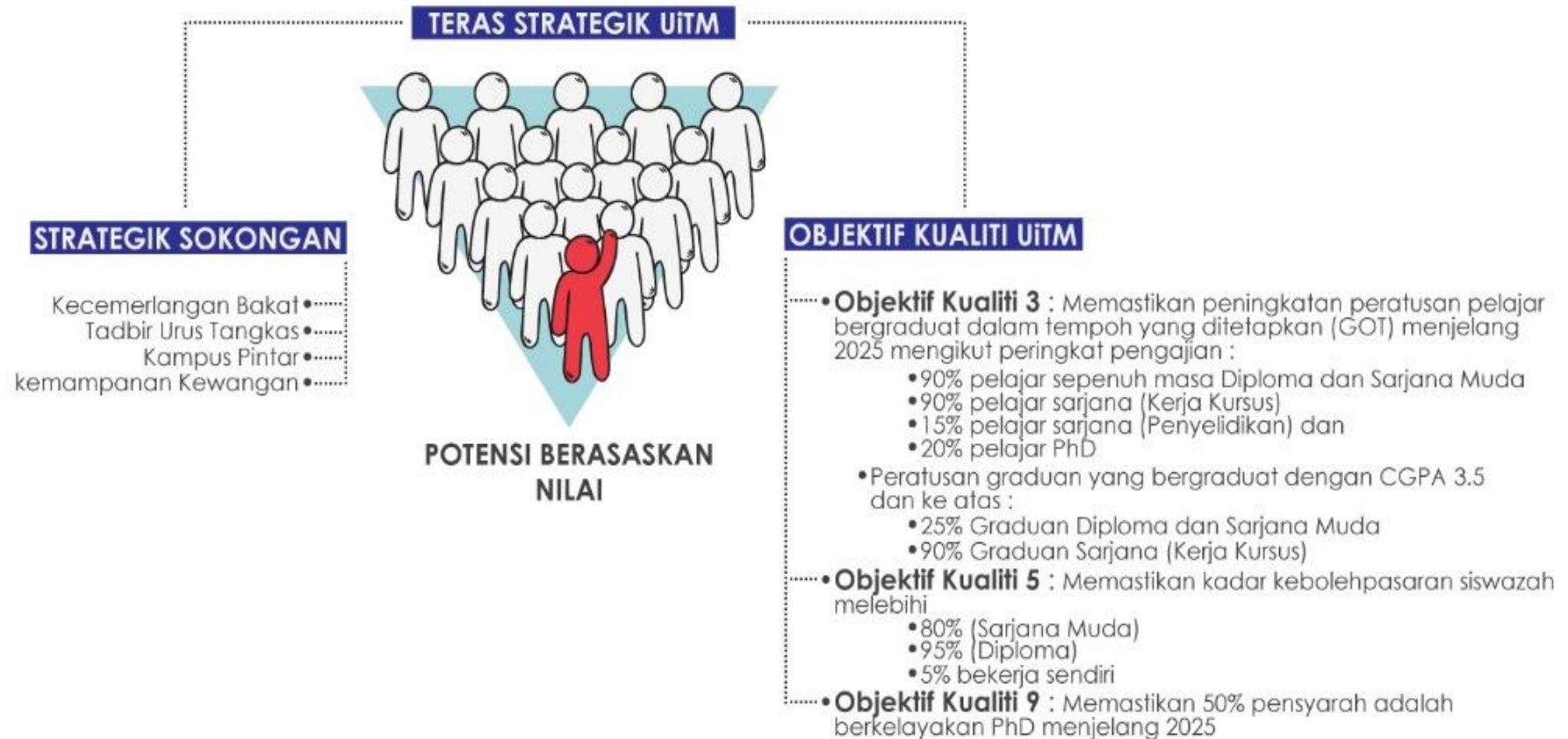
OBJEKTIF KUALITI UiTM

- **Objektif Kualiti 1** : Mencapai enrolmen 200,000 pelajar menjelang 2025
 - 60% pelajar yang memperolehi 5A di peringkat SPM yang mendaftar bersama UiTM
- **Objektif Kualiti 2** : Memastikan 100% kurikulum melalui proses semakan sekurang-kurangnya sekali dalam 3-5 tahun
 - Peningkatan bilangan program yang mendapat pengiktirafan daripada badan-badan profesional tempatan dan antarabangsa :
 - Tempatan : 40 program
 - Antarabangsa : 27
- **Objektif Kualiti 3** : Memastikan peningkatan peratusan pelajar bergraduasi dalam tempoh yang ditetapkan (GOT) menjelang 2025 mengikut peringkat pengajian :
 - 90% pelajar sepenuh masa Diploma dan Sarjana Muda
 - 90% pelajar sarjana (Kerja Kursus)
 - 15% pelajar sarjana (Penyelidikan) dan
 - 20% pelajar PhD
 - Peratusan graduan yang bergraduasi dengan CGPA 3.5 dan ke atas :
 - 25% Graduan Diploma dan Sarjana Muda
 - 90% Graduan Sarjana (Kerja Kursus)
- **Objektif Kualiti 5** : Memastikan kadar kebolehpasaran siswazah melebihi
 - 80% (Sarjana Muda)
 - 95% (Diploma)
 - 5% Bekerja sendiri

PEMETAAN OBJEKTIF KUALITI UiTM TERHADAP TERAS STRATEGIK UiTM



PEMETAAN OBJEKTIF KUALITI UiTM TERHADAP TERAS STRATEGIK UiTM



STRUCTURE OF ISO 9001 : 2015

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

1. 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

STRUCTURE OF ISO 9001 : 2015

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

STRUCTURE OF ISO 9001 : 2015

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

ISO 9001:2015 Clause 4

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

UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT – 4.1

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.

SWOT ANALYSIS

SWOT analysis

STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
What does your organization do better than your competition?	What does your organization need to improve upon?	What market trends could lead to increased sales?	What are the advantages competitors have over your organization?

SWOT ANALYSIS

	HELPFUL (for your objective)	HARMFUL (for your objective)
INTERNAL (within organisation)	Strengths <ul style="list-style-type: none">• — Budget/Finance• — Infrastructure• — Technology• — Manpower – Competency• — Team Work Culture• — Working Environment• — Communication	Weaknesses <ul style="list-style-type: none">• — Customer Feedback• — Infrastructure• — Technology• — Manpower – Competency• — Team Work Culture• — Working Environment• — Communication
EXTERNAL (outside organisation)	Opportunities <ul style="list-style-type: none">• — New Technology• — New Government Policy• — Social Patterns• — Population Profile• — Location• — Local Activities	Threats <ul style="list-style-type: none">• — New Legislation• — Economy Crisis• — Contractors• — Supplier• — Better service from outside

4.2 – UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

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.

4.3 – DETERMINING THE SCOPE QMS

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.

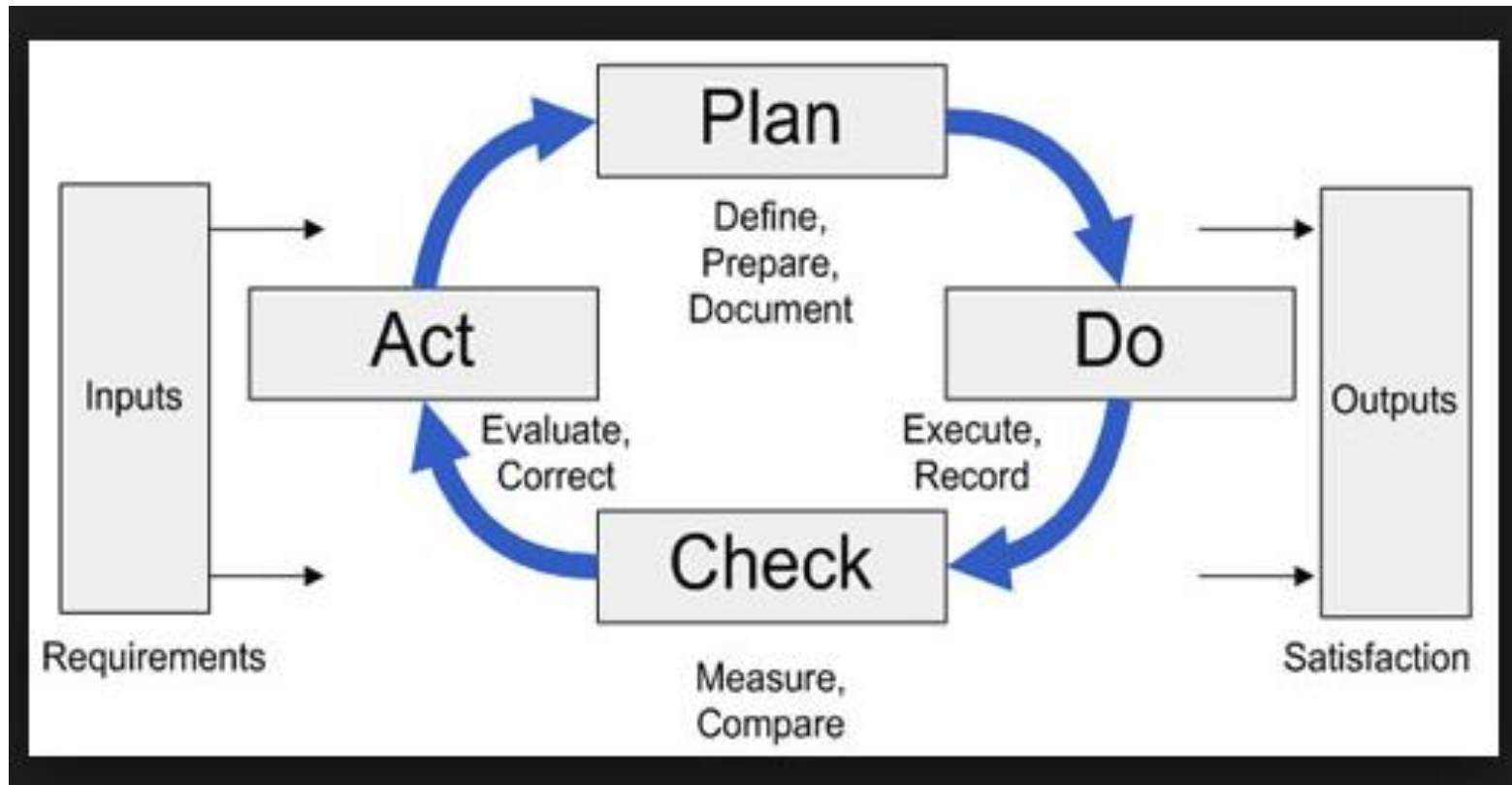
4.4 – QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

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

PROCESS APPROACH



Evidences: Vision, Mission, Strategic Planning, Management Meeting, CQI report, Research Policy etc.

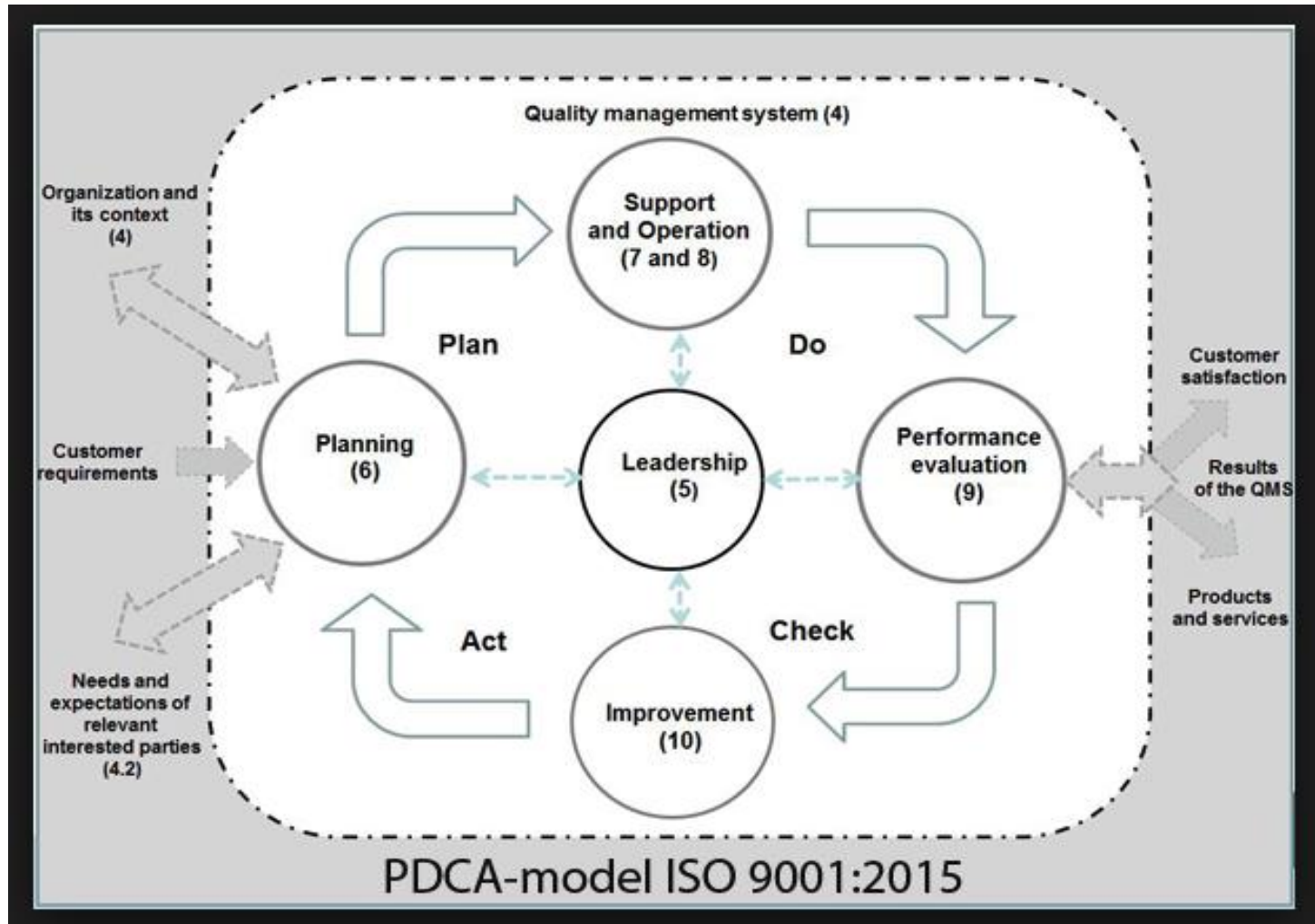
CLAUSE 5 : LEADERSHIP



5. LEADERSHIP



ISO 9001 : 2015 PROCESS MODEL



5.1 : LEADERSHIP AND COMMITMENT

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

5.1.2 : CUSTOMER FOCUS

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 : QUALITY POLICY

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.

5.3 : ORGANIZATIONAL ROLES, RESPONSIBILITIES & AUTHORITIES

- 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.

CLAUSE 6 : PLANNING



6. PLANNING



6.1

Actions to
address
risks and
opportunities

Quality
objectives
and planning
to achieve them

6.2

Planning
of
changes

6.3

6.1 : ACTION TO ADDRESS RISK AND OPPORTUNITIES

- 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.

6.2 QUALITY OBJECTIVE AND PLANNING TO ACHIEVE THEM

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 QUALITY OBJECTIVE AND PLANNING TO ACHIEVE THEM

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?

6.3 PLANNING OF CHANGES

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.

CLAUSE 7 : SUPPORT

7.1 Resources

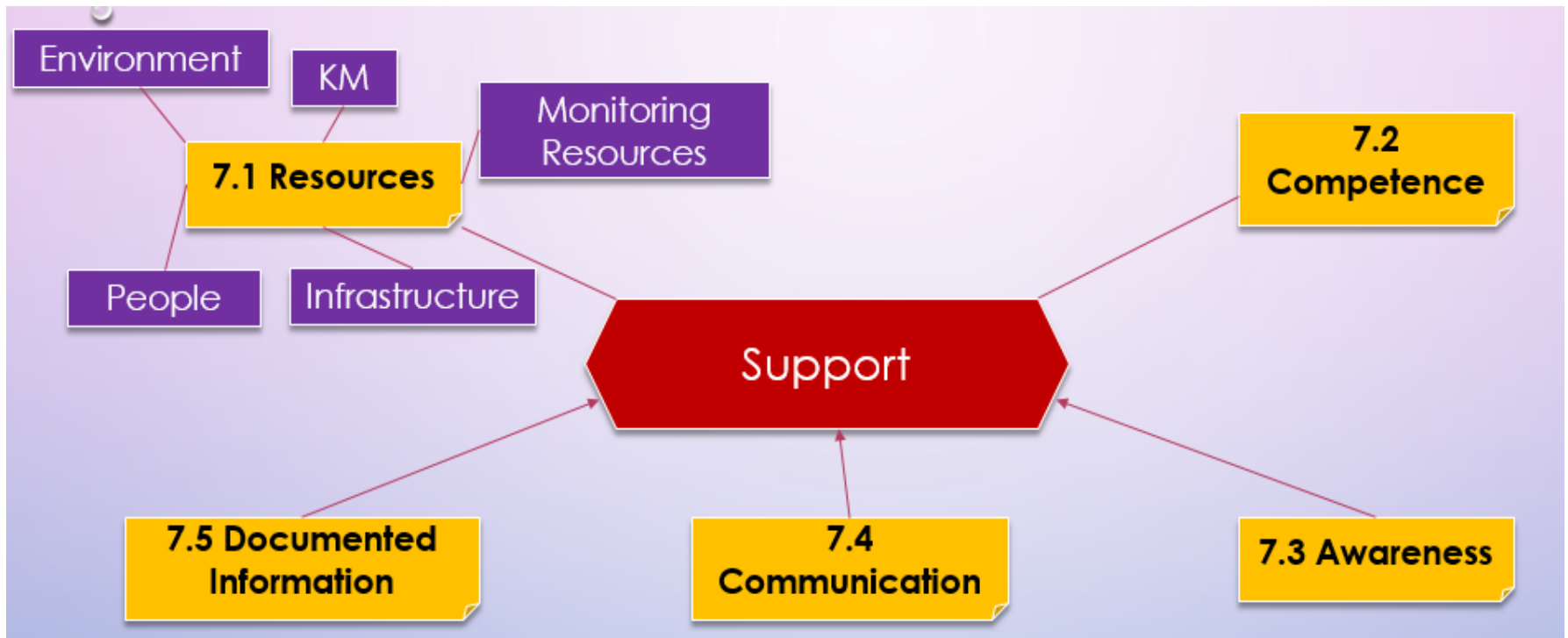
Competence 7.2

7.3 Awareness

Communication 7.4

7.5 Documented Information

SUMMARY



7.1 RESOURCES

- 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.

7.1.2 PEOPLE

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.

7.1.3 INFRASTRUCTURE

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.

7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

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.

7.1.5.1 MONITORING AND MEASURING RESOURCES

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)

7.1.5.2 MEASUREMENT TRACEABILITY

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.

7.1.6 ORGANIZATIONAL KNOWLEDGE

- 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

7.2 COMPETENCE

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.

7.3 AWARENESS

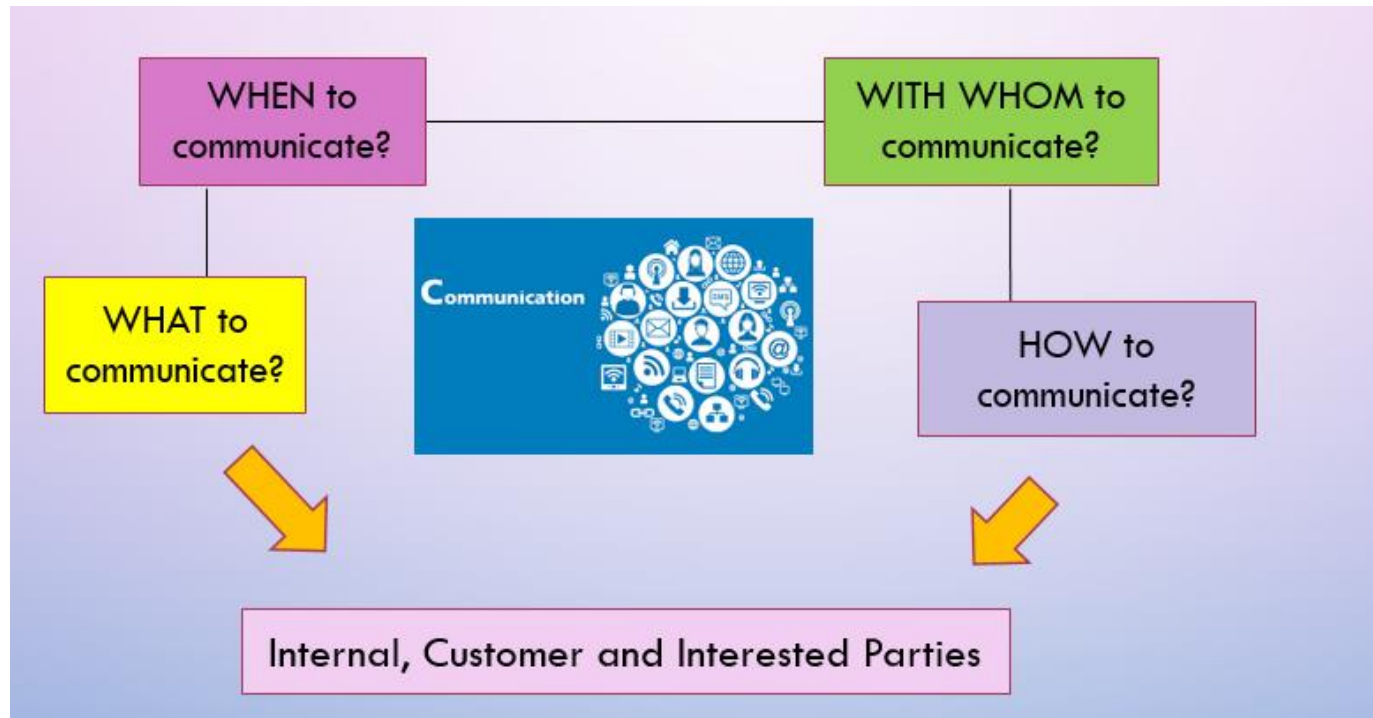
The persons doing work under the organization's control shall have awareness on:

- 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.

7.4 COMMUNICATION

- Includes internal and external Communication relevant to QMS



Evidences: Meeting, Website, Notice Board, Workshop, Briefing, Poster, Banner, etc.

7.5 DOCUMENTED INFORMATION

- More flexible in documentation



- 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 DOCUMENTED INFORMATION

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

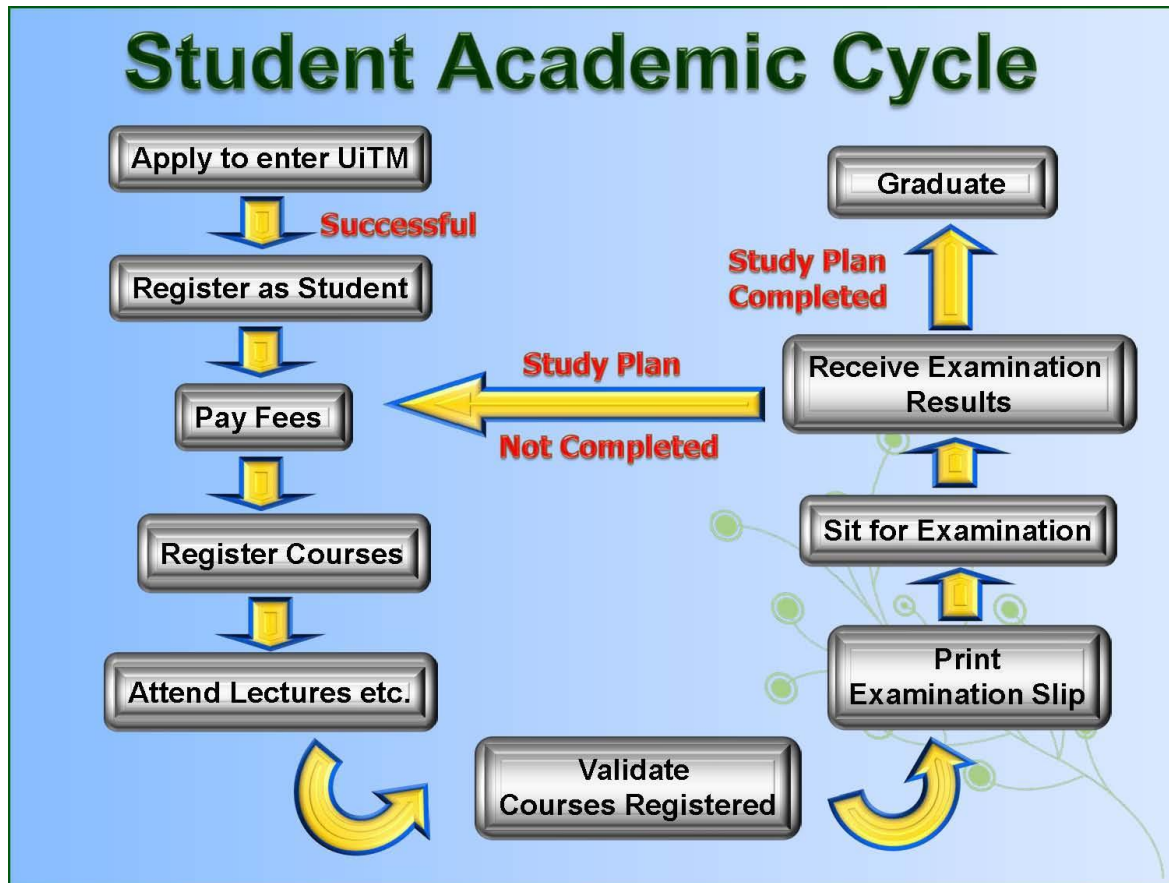
Storage,
preservation,
legibility

Version
Control

Retention &
disposition

Includes documented information of external origin

CLAUSE 8 : OPERATION



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

8.1 OPERATIONAL PLANNING AND CONTROL

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.

8.2.2 DETERMINATION OF REQUIREMENTS RELATED TO PRODUCT AND SERVICES

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.

8.2.3 DETERMINATION OF REQUIREMENTS RELATED TO PRODUCTS AND SERVICES

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.

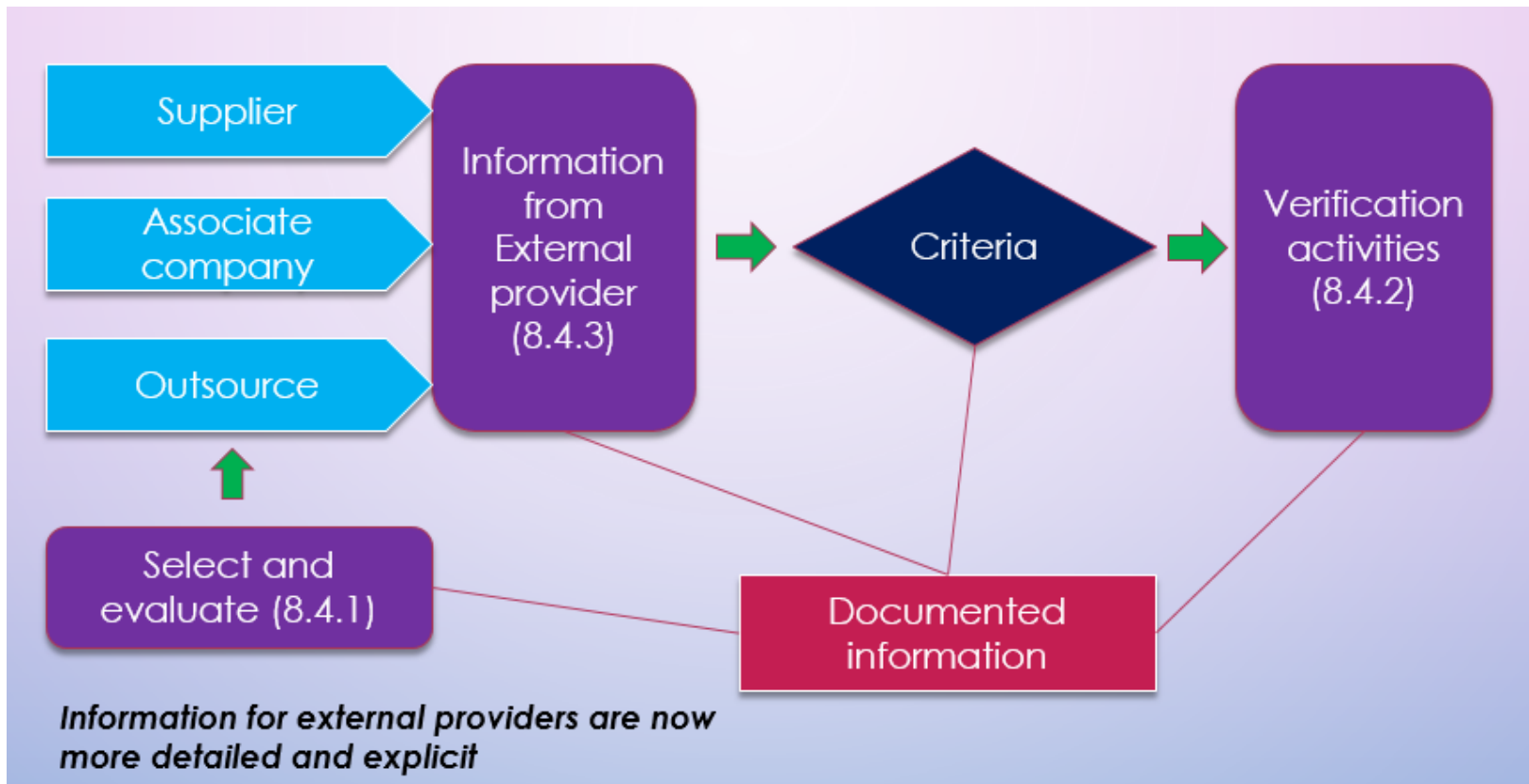
8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

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 combining 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.

8.4 CONTROL OF EXTERNAL PROVISION OF GOODS AND SERVICES



8.5.1 CONTROL OF PRODUCTION AND SERVICES PROVISION

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.

8.5.2 IDENTIFICATION AND TRACEABILITY

- 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.

8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

- 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.

8.5.4 PRESERVATION

- 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.

8.5.5 POST DELIVERY ACTIVITIES

- 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

8.5.6 CONTROL OF CHANGES

- 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.)

8.6 RELEASE OF PRODUCTS AND SERVICES

- 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 pemeriksaan, Surat Konvo, Program Baru, Etc.)

8.7 CONTROL OF NONCONFORMING PROCESS OUTPUTS, PRODUCTS AND SERVICES

- 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**

CLAUSE 9 : PERFORMANCE EVALUATION



CLAUSE 9 : PERFORMANCE EVALUATION

9. PERFORMANCE EVALUATION



Monitoring, measurement,
analysis and
evaluation



Internal
Audit



Management
review



9.1 MONITORING, MEASUREMENT, ANALYSIS & EVALUATION

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.

9.1.2 CUSTOMER SATISFACTION

- 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.**

9.1.3 ANALYSIS AND EVALUATION

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.

9.2 INTERNAL AUDIT

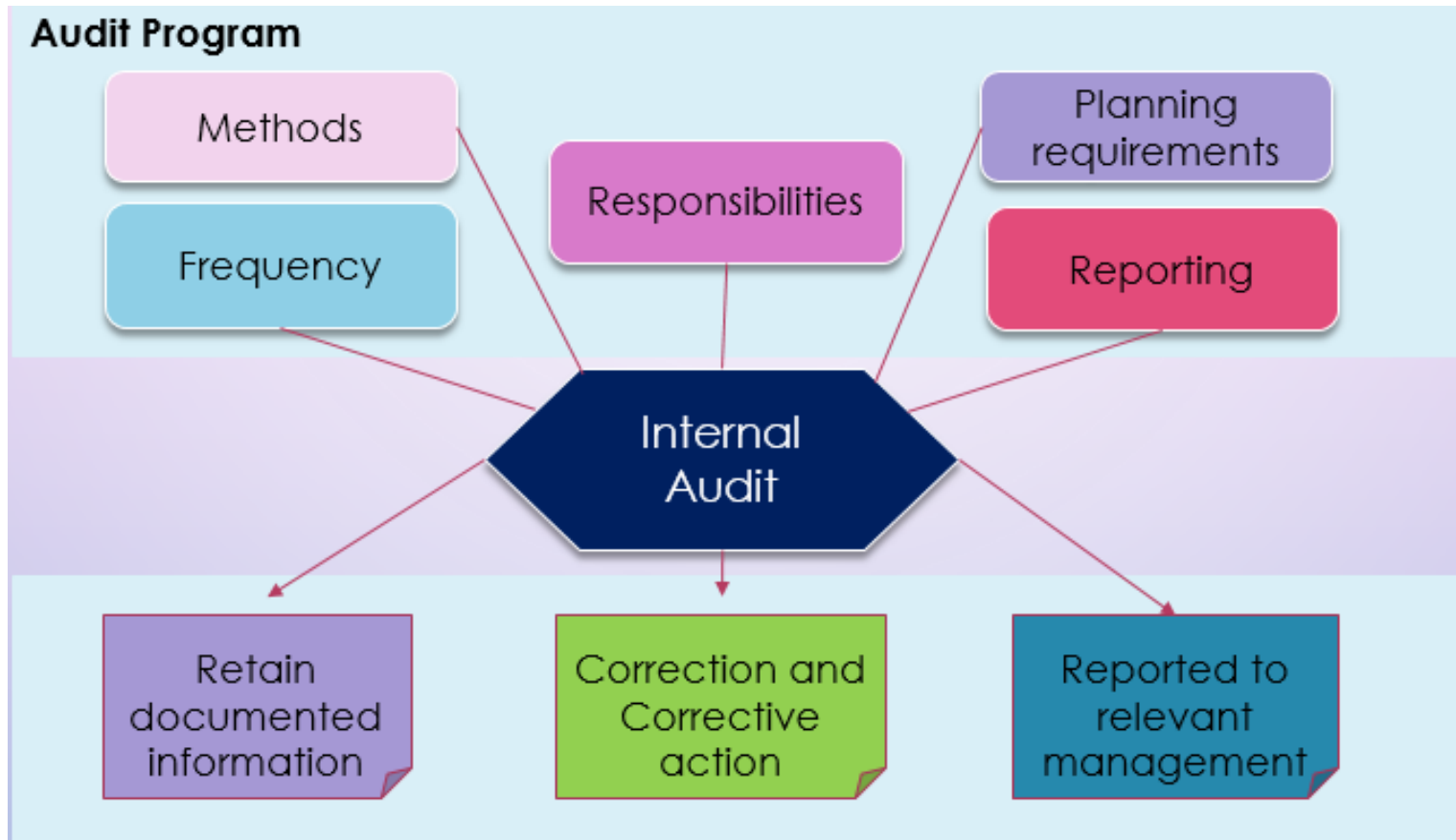
The organization shall conduct Internal Audit at planned intervals to ensure that the organization's requirements and the requirements of this standard, are met and the QMS is effectively implemented and maintained.

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.

9.2 SUMMARY OF INTERNAL AUDIT



9.3.2 MANAGEMENT REVIEW INPUTS

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.

9.3.3 MANAGEMENT REVIEW OUTPUTS

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.

CLAUSE 10 : IMPROVEMENT



10. IMPROVEMENT

10.1  General

Nonconformity and corrective action

10.2 

10.3  Continual improvement

CLAUSE 10 : 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)***

10.2 NONCONFORMITY AND CORRECTIVE ACTION

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

10.3 CONTINUAL IMPROVEMENT

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.*

ANY
QUESTIONS
?

DOA PENUTUP

سُبْحَانَكَ اللَّهُمَّ وَبِحَمْدِكَ أَشْهَدُ أَنْ لَا إِلَهَ إِلَّا أَنْتَ أَسْتَغْفِرُكَ وَأَتُوبُ 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.

Terima Kasih

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