UNDERSTANDING & IMPLEMENTING OF ISO 9001:2015



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1

COURSE OBJECTIVES

1. To provide understanding on the general concept of ISO 9001:2015 Management System;
2. To understand the implementation requirements of ISO 9001:2015.

2

At the end of the course, participants should be able to...

1. Understand the requirements of ISO 9001:2015;
2. Establish and implement QMS based on the ISO 9001:2015 requirements.

3

INTRODUCTION TO ISO 9001:2015

4

BACKGROUND

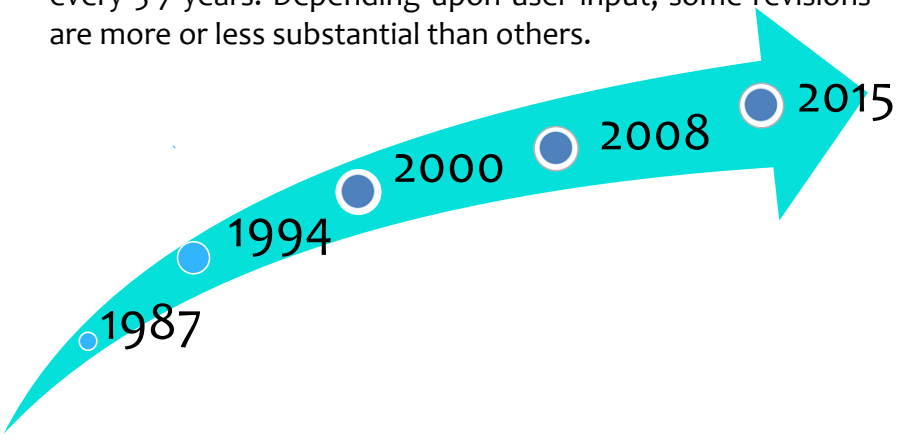
- First published in 1987, ISO 9001 has consistently been ISO's most popular series of standards.
- Building on years of success, ISO technical committee ISO/TC 176, Quality Management System and Quality Assurance, subcommittee SC 2, Quality System is busy laying groundwork for the next generation of quality management system.

Aim of ISO 9001:2015

5

ISO 9001 IS CHANGING?

- ISO Standards are reviewed for suitability and effectiveness every 5-7 years. Depending upon user input, some revisions are more or less substantial than others.



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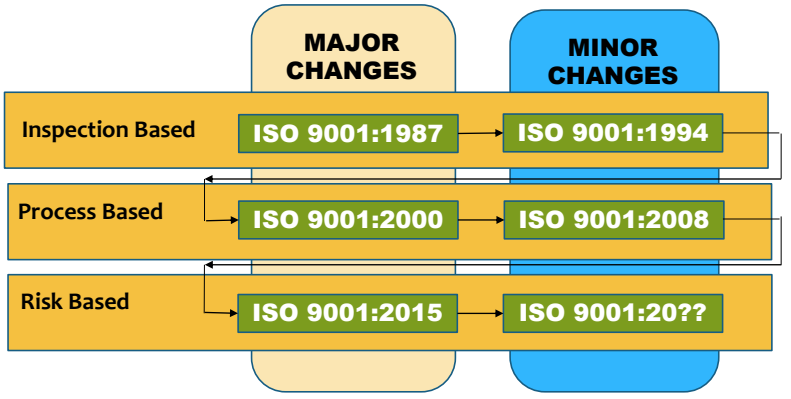
ISO 9001 development process



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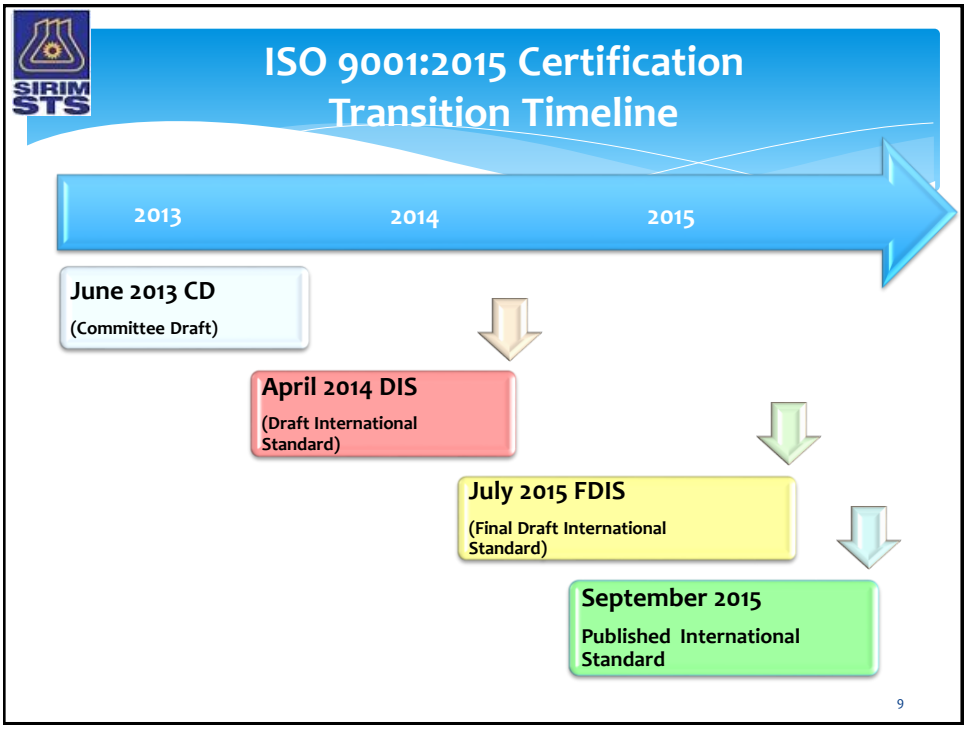
ISO 9001 development process

- There are several distinct stages when developing ISO standard; the key ones being:
  1. Working Drafts (WD)
  2. Committee Drafts (CD)
  3. Draft International Standard (DIS)
  4. Final Draft International Standard (FDIS)
  5. International Standard (IS)

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

8


ISO 9001:2015 Certification Transition Timeline
2013
2014
2015
June 2013 CD
(Committee Draft)
April 2014 DIS
(Draft International Standard)
July 2015 FDIS
(Final Draft International Standard)
September 2015
Published International Standard
9


ISO 9001:2015 Certification Transition Timeline
2015
2016
2017
2018
September 2015
Published International Standard
September 2015 start of 3 years transition period to September 2018
• Certifications to ISO 9001:2008 will no longer be valid after September 2018
10

ISO 9001:2015 Interaction

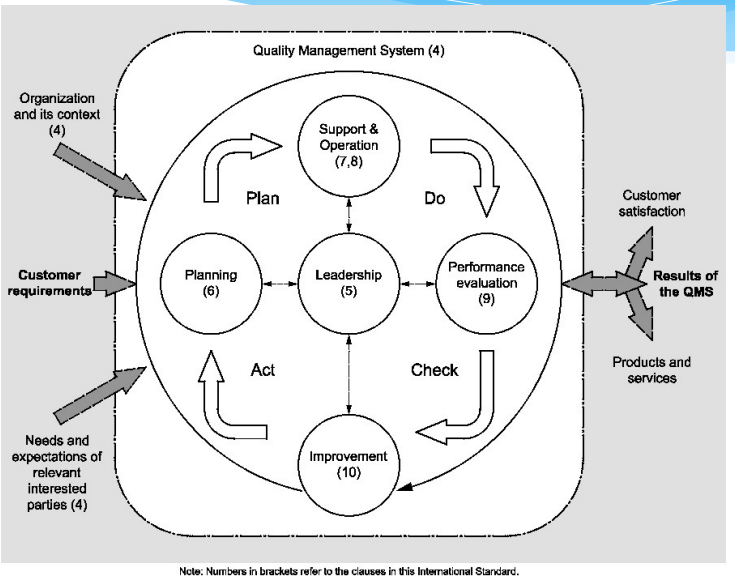
Customer and Legal Requirements

ISO 9001:2015 Standard Requirement

Risk and opportunities

11

ISO 9001:2015 process model



Note: Numbers in brackets refer to the clauses in this International Standard.

12

Quality principles

- **QMP1. Customer Focus –** The primary focus of Quality management is to meet customer requirements and to strive to exceed customer expectation.
- **QMP2. Leadership** – Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives of the organization.
- **QMP3. Engagement of People –** It is essential for the organization that all people are competent, empowered and engaged in delivering value.

13

Quality principles

- **QMP4. Process Approach –** Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as coherent system.
- **QMP5. Improvement** – Successful organizations have an ongoing focus on improvement.
- **QMP6. Evidence based Decision Making –** Decision based on the analysis and evaluation of data and information are more likely to produce desired result.

14

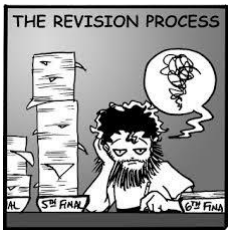
Quality principles

- **QMP7. Relationship Management –** For sustained success, organizations manage their relationships with interested parties, such as suppliers.

15

Common clause titles for all MS

0. Introduction
1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement



16

High Level Structure

- A new common format has been developed for use in all management system standards

Standardized core text and structure
Standardized core definitions

Organizations implementing multiple management systems (e.g. quality. Environmental, information security) can achieve better integration and easier implementation

17

High Level Structure

- The high level structure has been used in published standards such as:

ISO 22301:2012 BCMS	ISO 20121:2012 ESMS
ISO 39001:2012 RTSMS	ISO 27001:2013 ISMS
ISO 55001:2014 AMS	ISO 9001:2015 QMS
ISO 14001:2015 EMS	ISO 45001:2016 OHSMS
ISO 37001:2016 ABMS	ISO 22000:2018 FSMS

18

Structure of ISO 9001:2015 (1/3)

1 **Scope**
2 **Normative references**
3 **Terms and definitions**
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 policy
- 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

19

Structure of ISO 9001:2015 (2/3)

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 requirements 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 service provision
- 8.6 Release of products and services
- 8.7 Control of non conforming process outputs, products and services

20

Structure of ISO 9001:2015 (3/3)

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

21

CLAUSE 1 : SCOPE

22

Scope - 1

* Specifies requirements for a Quality Management System when an organization

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements

b) aims to enhance customer satisfaction through the 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

23

Scope - 1

* All the requirements are generic and are intended to be applicable to any organization, regardless of its

- Type
- Size
- Products
- Services it provides

24

CLAUSE 4 : CONTEXT OF THE ORGANIZATION

25

Context of the organization -4.1

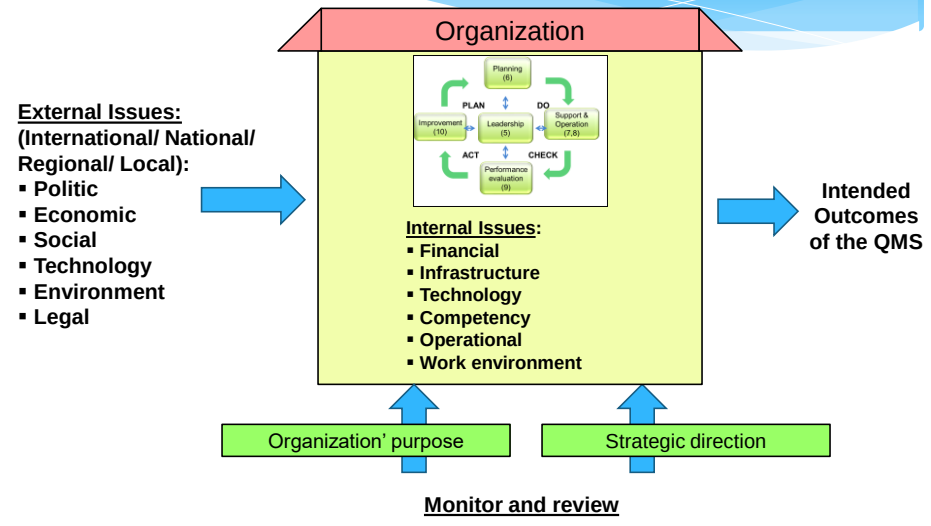
Context of the organization clauses – include determination of **external and internal issues** relevant to the organization's purposes and strategic direction; more akin to business management system than a silo quality management system.

The organization is expected to monitor and review information relating to :

- internal and external issues relevant to its purpose

26

4.1 Understanding the organization and its context



27

Organization context

No	Ext. Issue	Example
1	Politic	- Overlapping fields of power and opinion between ministries - NKRA achievements
2	Economic	- The implementation of GST - Currency exchange
3	Social	- Uncontrolled influx of foreigners
4	Technology	- Spreading false information that is not controlled
5	Environment	- Haze - Flooding
6	Legal	- The law restricted / limited power

28

SWOT Analysis

Internal

External

Strengths	: characteristics of an organization that can help the organization achieve its objectives
Weaknesses	: characteristics of an organization that fails to achieve the objectives of the organization
Opportunities	: external conditions that can help organizations achieve their objectives
Threats	: external conditions that can make organizations fail to achieve their objective

9

Examples of internal issues

STRENGTHS	WEAKNESSES
1. Strong financial resources	1. Changing leadership
2. Competent, professional and integrity Human resources	2. Lack of cooperation between divisions/departments
3. ICT facilities	3. Limited financial resources
4. Attitudes to be competitive	4. Lack of skilled personnel
5. Efficient management	5. Lack of use latest technology
6. Comprehensive management system	6. Office space is narrow and limited
7. Enough and experienced staff	7. Limited career prospects
8. Dynamics leadership	8. Limited work equipment
9. Teamwork and high commitment staff	

30

Examples of external issues

OPPORTUNITIES	THREATS
1. High provision of youth development program. 2. There are many agencies involved in youth development. 3. There is a national research center to study the various aspects of the flow and the development of the younger generation.	1. Trends and youth culture that frequently change. 2. Great age gaps of youth organizations led by veteran young people. 3. The public perception that youth are seen as people who pose problems. 4. Youth development programs that cannot attract the attention and involvement of the youth.

31

4.2 Understanding the needs and expectations of interested parties

The Organization Shall determine:

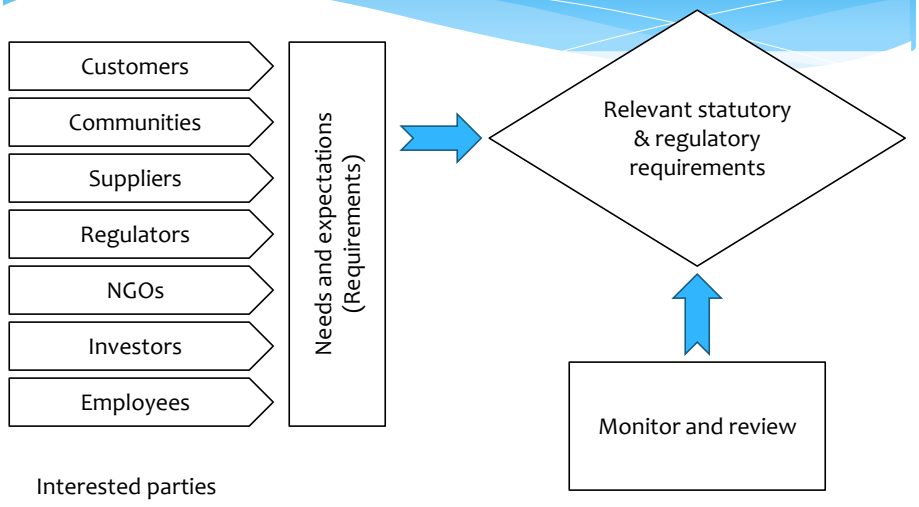
- The interested parties that are relevant to the quality management system
- The requirements of these interested parties that are relevant to the quality management system.

The organization is expected to monitor and review information relating to internal and external issues and the requirements of relevant interested parties that may have an impact on the ability of the QMS to achieve intended results

Only need to address particular requirements of relevant interested parties if the requirements have an impact or potential impact on the ability of the organization to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

32

4.2 Understanding the needs and expectations of interested parties



33

Examples of Interested Parties

- Jabatan Kerja Raya
- Jabatan Pengairan dan Saliran
- Jabatan Bomba
- Indah Water Konsortium
- Jabatan Perancangan Bandar dan Daerah
- MAMPU
- Jabatan Pengurusan Sisa Pepejal
- Jabatan Kesihatan Negeri
- Pejabat Daerah
- Polis Diraja Malaysia
- Jabatan Audit Negara

34

Examples of statutory & regulatory requirements

- Akta Kerajaan Rasmi 1972 (Akta 171)
- Akta Jalan, Parit dan Bangunan 1974 (Akta 133)
- Akta Perancangan Bandar dan Desa (Akta 172)
- Akta Rahsia Rasmi 1972
- Akta Arkib Negara 2003
- Akta Kanun Keseksaan (Akta 574)
- Akta Rahsia Rasmi 1972 (Akta 88)

35

4.3 Determining the scope

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

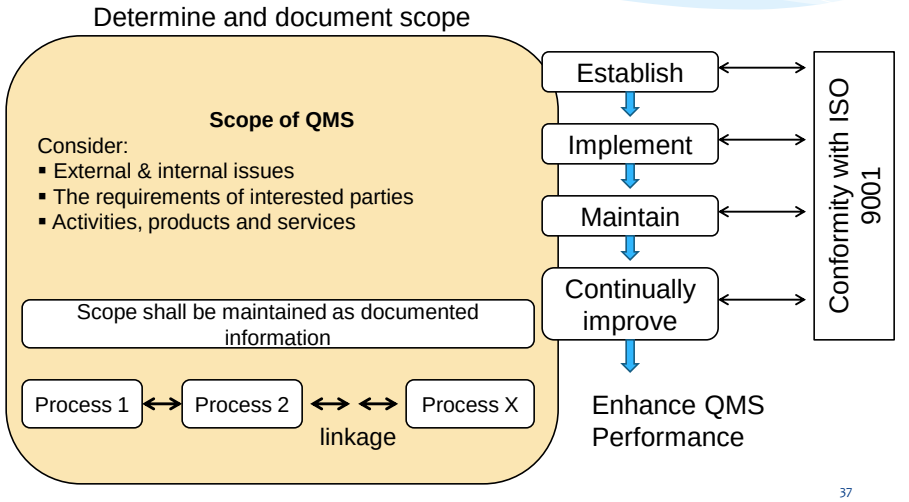
- External and internal issues
- Relevant requirements of interested parties
- Its products and services

There is no explicit provision for exclusion of requirements

All requirements of the standard within the determined scope which can be applied shall be applied by the organization.

36

Determining the scope of QMS



37

4.4 Quality Management System

The new standard further promote the process approach beyond the existing requirements in ISO 9001:2015. The organization shall determine:

- The processes needed for the QMS
- The inputs and outputs of the processes
- The sequence and interaction of the processes
- The criteria, methods, including measurements and related performance indicator
- The resources needed
- The assignment of the responsibilities and authorities
- The risks and opportunities
- The method for monitoring, measuring and evaluation
- Opportunities for improvement

38

CLAUSE 5: LEADERSHIP

39

Who is Top Management?

Definition 1:

Individual or group of people who set the direction of an organization

Definition 2:

Individual or group of people that provide roles and responsibility for staffs

Source: ISO 19011

40

5.1 LEADERSHIP & COMMITMENT

Top management to demonstrate leadership and commitment by:

- taking accountability for the effectiveness of the QMS
- ensuring compatibility of policy & objectives with strategic direction and context
- Ensuring resources needed are available
- integration of the QMS into organization's business processes
- promoting awareness of the process approach
- involvement of people in QMS
- promotion of continual improvement
- supporting other management roles to demonstrate their leadership

41

5.1.2 CUSTOMER FOCUS

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

- Customer requirements and applicable statutory and regulatory are determined and met
- The risks and opportunities that can affect conformity of product and services and the ability to enhance customer satisfaction are determined and addressed.
- The focus on enhancing customer satisfaction is maintained.

42

5.2 QUALITY POLICY

* Top management shall establish Quality policy that:
  * Appropriate to the purpose and context of the organization
  * Provide a framework for setting and reviewing the quality objectives.
  * Includes a commitment to satisfy applicable requirements.
  * Include a commitment to continual improvement

43

5.2.2 QUALITY POLICY

* The Policy shall:
  * Be available as documented information
  * Be communicated, understood and applied within the organization
  * Be available to interested parties as appropriate.

44

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 and authority for:

a) Ensuring that QMS conforms to the requirements
b) Ensuring the processes are delivering their intended outputs
c) Reporting the performance, including recommendation for improvement
d) Ensuring the promotion of customer focus
e) Ensuring the integrity are maintain

45

CLAUSE 6 : PLANNING

46

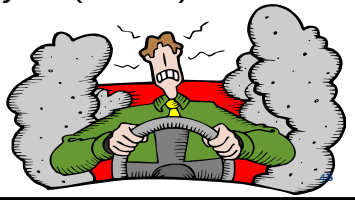
6.1 Action to address risk and opportunities

* When planning of QMS, shall consider the issues referred to 4.1 and 4.2 and determine the risks and opportunities that need to be addresses to:
  * Ensure the QMS can achieve its intended outcome
  * Enhanced desired effects
  * Prevent or reduce undesired effects
  * Achieve continual improvement

47

EXAMPLE OF TECHNIQUE

- Hazard Identification, Risk Assessment and Determining Control (HIRADC)
- Hazard and Operability Study (HAZOP).
- Hazard Analysis Critical Control Points (HACCP)
- Aspect And Impact - ISO 14000
- Hazard Analysis - OHSAS 18000
- Fault Tree Analysis (FTA)
- Failure Mode and Effect Analysis (FMEA)



Risk Assessment Format

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/ Likelihood/ Frequency	Severity/ Impact	Risk Level	Mitigation Plan/ Additional Control	PIC (Due Date/Status)

49

Description of probability / likelihood

Rating	Likelihood	Description
5	Almost certain	Happens repeatedly at the location @ At least once a month @ Daily exposure
4	Likely	Actual event frequency at the location is at least once every year @ Once every 6 months @ Weekly exposure
3	Moderate	Actual event frequency at the location is at least once every 3 years @ Once every year @ Monthly exposure
2	Unlikely	Has occurred in the company and may occur on site @ Isolated occurrence on site @ Yearly exposure
1	Rare	Has occurred in the industry @ Unlikely to occur on site @ Never happened

50

Eg: Description of probability / likelihood (MOA)

Skala Penarafan		Keterangan
5	Hampir pasti	Sesuatu kejadian yang kemungkinan berlaku sekali dalam sebulan
4	Kemungkinan tinggi	Sesuatu kejadian yang kemungkinan berlaku sekali dalam 3 bulan
3	Ada kemungkinan	Sesuatu kejadian yang kemungkinan berlaku sekali dalam 2 tahun
2	Kemungkinan rendah	Sesuatu kejadian yang rendah kemungkinan berlaku sekali dalam 3 tahun
1	Jarang	Sesuatu kejadian yang jarang berlaku sekali dalam lebih 3 tahun

51

Description of severity

Rating	Severity	Description
5	Catastro-phic	- Potential failure mode - Affect safety - Involve noncompliance with government regulation
4	Major	- Line shutdown or stop ship - 100% of product have to be scrapped - Loss of primary function on product - Customer complaints
3	Moderate	- A portion of the production may have to be scrapped - Deviation from primary process - Delay in delivery/ production
2	Minor	- Product have to be reworked - Degradation of product function - Reduce level of product performance
1	Insignifi-cant	- No discernible effect

52

Eg: Description of severity (MOA)

	Skala Penarafan	Keterangan
5	Sangat besar	Pelanggaran Undang – Undang atau menjejaskan reputasi atau boleh menyebabkan kemalangan
4	Besar	Perkhidmatan tidak dapat disempurnakan hingga menyebabkan ketidakpuasan hati / aduan pelanggan
3	Sederhana	Perkhidmatan lewat tetapi masih dapat disempurnakan
2	Kecil	Perkhidmatan disempurnakan tetapi kurang lengkap
1	Sangat Kecil	Tidak memberi kesan

53

Likelihood and Impact Matrix

Severity →

Likelihood ↑

		INSIGNIFI-CANT	MINOR	MODERATE	MAJOR	CATASTRO-PHIC
		1	2	3	4	5
5	ALMOST CERTAIN	5	10	15	20	25
4	LIKELY	4	8	12	16	20
3	MODERATE	3	6	9	12	15
2	UNLIKELY	2	4	6	8	10
1	RARE	1	2	3	4	5

54

Risk Acceptance Rates

Risk Level	Risk Scale	Risk Explanation
EXTREME	**16-25**	The risk is very high, a detailed action plan needed
HIGH	**10-15**	High risk, the attention of top management needed
MEDIUM	**5-10**	Moderate risk, managed by person in charge
LOW	**1-5**	Low risk, managed in accordance with existing procedures

55

6.2 Quality Objective and Planning

* The organization shall establish Quality objectives at relevant function and levels.
* 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 update as appropriate

56

6.2 Quality Objective and Planning

* When planning, the organization shall determine:
  * What will be done
  * What resources will be required
  * Who will be responsible
  * When it will be completed
  * How the results will be evaluated

57

6.3 Planning of changes

- Where determines the need of change to the quality management system, the change shall carried out in a planned and systematic manner. Shall consider :
  - The purpose of the change and any potential consequences
  - The integrity of the quality management system
  - The availability of resources
  - The allocation or reallocation of responsibilities and authorities

58

CLAUSE 7 : SUPPORT

59

7.1 Resources

There should be adequate resources to ensure effectiveness of the management system.

Resource considerations now include:

1. Capability of and constraints on existing internal resources
2. Need for external providers

60

7.1.2 People

7.1.2 People

- Essentially not a new requirement – mainly for alignment with the QMPs
- Organization shall provide persons necessary for the effective operation of the QMS, including the processes needed - to ensure it can consistently meet customer and applicable statutory / regulatory requirements.

61

7.1.3 Infrastructure

- Shall determine, provide and maintain infrastructure for the operation of its processes to achieve conformity of products and services.
- Can include building, associated facilities, equipment including hardware and software, transportation, information and communication technology

62

7.1.4 Environment for the operation of processes

- Shall determine, provide and maintain the environment necessary for the operation.
- Can include physical, social, psychological, environmental and other factor (such as temperature, humidity, ergonomic and cleanliness)

63

7.1.5 Monitoring and measuring resources

Shall determine resources needed to ensure valid and reliable monitoring and measuring results.

Shall ensure the resources provided:

- Are suitable
- Maintained to ensure continued fitness for their purpose

Shall retain appropriate documented information of fitness for purpose of monitoring and measuring resources.

- Shall provide traceability when it is a requirement
- Shall verified or calibrated at specified interval
- Identified their calibration status
- Safeguarded from adjustments, damage or deterioration

64

7.1.6 Organizational knowledge

- Not the same as 'competence' – which relates to the knowledge of an individual.
- Requirement for organization to **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.

65

7.2 Competence

- Shall determine the necessary competence of person(s) doing work under its control that affects its QMS performance.
- Ensure these persons are competence on the basis of appropriate education, training or experience.
- Take action to acquire the necessary competence and evaluate the effectiveness.
- Retain appropriate documented information as evidence of competence.

66

7.3 Awareness

- Persons doing work shall be aware:
  - The Quality policy
  - The relevant quality objective
  - Their contribution to the effectiveness of QMS
  - The implication of not conforming with QMS requirements

67

7.4 Communication

- Shall determine the need for internal and external communications relevant to QMS, including:
  - On what it will communicate
  - When to communicate
  - With whom to communicate
  - How to communicate

68

7.5 COMMUNICATION (EXAMPLE)

Interpretation

- Internal communication:
  - i. Regular meeting
  - ii. Newsletter
  - iii. Intranet sites
  - iv. Consultation, Briefing
- External communication:
  - i. Dialogue with interested parties
  - ii. Campaign
  - iii. Road tour

69

7.5 DOCUMENTED INFORMATION

7.5.1 General

* The QMS management system shall include:
  * Documented information required by the international standard.
  * Documented information determined by the organization as being necessary for the effectiveness of the QMS management system.

70

7.5.2 CREATING AND UPDATING

* When creating and updating documented information, the organization shall ensure appropriate:
  * Identification and description (e.g. title, date, author, or reference number)
  * Format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
  * Review and approval for sustainability and adequacy.

71

7.5.3 CONTROL OF DOCUMENTED INFORMATION

* Documented information required by the QMS management system and by this International Standard shall be controlled to ensure:
  * It is available and suitable for use, where and when it is needed.
  * It is adequately protected (e.g from loss of confidentiality, improper use or loss of integrity)
  * Distribution, access, retrieval and use.
  * Control of changes (e.g. version control)
  * Retention and disposition.

72

CREATING, UPDATING AND CONTROL OF DOCUMENTED INFORMATION

1. Preparation (format, content), verification, identification and approval
2. Distribution list
3. Control of document master list
4. Issuance control numbering system
5. Control of obsolete document
6. Control of external document
7. History page - Reason for changes & Details of changes
8. Review of draft copy by users
9. Issue No./Revision No.
10. Verify by relevant authorities
11. Inform and distribute new issues to users and destroy obsolete copies
12. Document stamping
13. Update master lists

73

CLAUSE 8: OPERATION

74

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:
  - Determining requirements for the product and services
  - Establishing criteria for the processes and for the acceptance of product/service
  - Determining the resources needed
  - Implementing control
  - Retaining documented information.

75

8.2.1 Customer Communication

- Shall determine and implement effective arrangements for communicating with customers in relation to:
  - Product or services information
  - enquiries/contract/order handling, including changes
  - Obtaining customer views and perceptions, including complaints
  - Handling or treatment of customer property, if applicable
  - Specific requirements for contingency actions, when relevant

76

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:
  - Product and service requirements and applicable statutory and regulatory requirements are defined;
  - It has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.

77

8.2.3: Review of requirements related to product and services

* The organization shall review;
  - Requirements specified by the customer, including the requirements for delivery and post delivery activities
  - Requirements not stated by the customer but necessary for specified or intended use, when known
  - Requirements specified by the organization
  - Statutory and regulatory requirements related to the product and service
  - Contract or order requirements differing from those previously expressed

78

8.2.3: Review of requirements related to product and services

* Organizations shall ensure that contract or order requirements differing from those previously defined are resolved.
* The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.
* All relevant documented information results of the review, including new requirements for the products and services must be maintained.

79

8.3 Design and development of products and services

Requirements have substantively changed :

- Clarification of the application of D&D requirements (Clause 8.3.1)
- D&D planning uses the terms "consider" rather than "determine" (Clause 8.3.2)
- D&D inputs – explicit requirements for internal and external resource needs, potential consequences of failure and level of control expected by customers (Clause 8.3.3)
- D&D controls – new clause combining Reviews, Verification & Validation (Clause 8.3.4)

80

8.4 Control of externally provided processes, products and services

Clause 8.4.1 – General

- The organizations shall ensure that the externally provided (process, product, service) conform to requirements.
- The organization shall determine the control to be applied to externally provided (process, product, service) when:
  a) Products and services from external providers are intended for incorporation into the organization's own products and services
  b) Products and services are provided directly to customers by external providers, on behalf of the organization
  c) A process or part of a process is provided by external provider, as a result of a decision by the organization
- The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with requirements.
- Documented information of these activities and any necessary actions arising from the evaluation, shall be retain.

81

8.4 Control of externally provided processes, products and services

Clause 8.4.2 – Type and extend of control

The organization shall:

a) Ensure that externally provided process within the control of QMS

b) Define control of external provider

c) Take into consideration:
   1. The potential impact of the externally provided processes, products and service.
   2. The effectiveness of the controls

d) Determine the verification or other activities to ensure that the externally provided processes, products and services meet requirements.

82

8.4 Control of externally provided processes, products and services

Clause 8.4.3 – Information for external providers

Relevant information needs to be communicated:

a) Processes, products and services to be provided
b) Approval of products and services, methods, processes and equipment, and the release of products and services
c) Competence, including relevant qualifications
d) The external providers' interaction with the organization
e) Control and monitoring of external providers' performance to be applied by the organization
f) Verification or validation activities that the organization, or customers intends to perform at the external providers' premises

83

8.5.1 Control of production and service provision

Shall plan and carry out production under controlled conditions.

Controlled conditions shall include:

a) Availability of documented information that defines characteristics of product or service, and results to be achieved
b) Availability and use of suitable monitoring and measuring resources
c) Implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products & services have been met
d) Use of suitable infrastructure and environment for the operation of processes
e) The appointment of competent persons, including any required qualification
f) Validation and periodic revalidation of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement
g) The implementation of actions to prevent human error
h) The implementation of released, delivery and post-delivery activities

84

8.5.2 Identification and traceability

- The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services
- The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision
- The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

85

8.5.3 Property belonging to customers or external providers

- The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.
- The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.
- When the property of customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

Note:
Customer-owned property, including materials, components, tools and equipment, premises, IP and private data.

86

8.5.4 Preservation

- Shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to the requirements.
- Can include identification, handling, contamination control, packaging, storage, transmission or transportation and protection.

87

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 consiquences associated with the products and services
c) The nature, use and intended lifetime of the products and services
d) Customer requirements
e) Customer feedback

88

8.5.6 Control of Changes

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

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

89

8.6 Release of products and services

The organization shall implement the planned arrangements at appropriate stages to verify that product and services requirements for verification have been met. Evidence of conformity with the acceptance criteria shall be retained.

The release of products and services to the customer shall not proceed until planned arrangements for verification of conformity have been completed unless otherwise approved by a relevant authority. Documented information shall provide traceability to the person authorizing.

90

8.7 Control of nonconforming outputs

The organization shall deal with nonconforming process outputs, products and services in one or more of the following ways:

- Correction
- Segregation, containment, return or suspension of provision of products and services
- Informing the customer
- Obtaining authorizing for
  - Use "as-is"
  - Release, continuation or re-provision of the products and service
  - Acceptance under concession

91

CLAUSE 9
PERFORMANCE EVALUATION

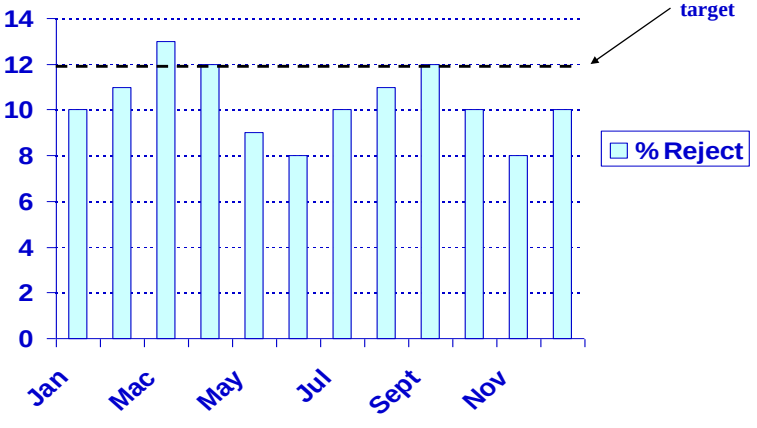
92

9.1 MONITORING, MEASUREMENT, ANALYSIS & EVALUATION

- The organization shall determine:
  - What need to be monitored and measured.
  - The methods for monitoring, analysis and evaluation as applicable
  - When the monitoring and measuring shall be performed
  - When the results from the monitoring and measurement shall be analysed and evaluated.
- Shall retain appropriate documented information as evidence of the results.
- Shall periodically evaluate compliance with applicable legal QMS requirements and other subscribed requirements

93

9.1 MONITORING, MEASUREMENT, ANALYSIS & EVALUATION



94

9.1.2 Customer Satisfaction

- The organization shall monitor customer perceptions of the degree to which requirements have been met.
- Shall obtain information relating to customer views and opinion of the organization and its products and services
- The methods for obtaining and using this information shall be determined
- Can include customer satisfaction/opinion survey, customer data on delivered products or service, market share analysis, compliments, warranty claims and dealer reports.

95

9.1.3 Analysis and Evaluation

- Shall analyse and evaluate appropriate data and information arising from monitoring, measurement and other sources.
- The output shall be used to:
  a) Demonstrate conformity of product and services to requirements
  b) Assess and enhance customer satisfaction
  c) Ensure conformity and effectiveness of the QMS
  d) Demonstrate successful planning
  e) Assess the performance of processes
  f) Assess the performance of external resources
  g) Determine the need for improvements

96

9.2 INTERNAL AUDIT

9.2.1 The organization shall conduct internal audit at planned intervals to provide information on whether the QMS:

a) Conforms to:

   1. The organization's own requirements for its QMS
   2. The requirements of this International Standard

b) Is effectively implemented and maintained

97

9.2 INTERNAL AUDIT

9.2.2 The organization must:

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

b) Define the audit criteria and scope for each audit

c) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process

d) Ensure that the results of the audits are reported to relevant management

e) Take appropriate correction and corrective action without undue delay

f) retain documented information as evidence of the implementation of the audit program and the audit results

Note: See ISO 19011 for guidance

98

9.3 Management Review

9.3.2 Management review inputs

Top management review 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 including its strategic direction
c) Information on quality performance:
    1) Customer satisfaction and feedback from relevant interested parties
    2) The extent to which quality objectives have been met
    3) Process performance and conformity of product and services
    4) Nonconformities and corrective actions
    5) Monitoring and measurement results
    6) Audit results
    7) The performance of external providers
d) The adequacy of resources
e) The effectiveness of actions taken to address risk and oportunities
f) Opportunities for improvement

99

9.3 Management Review

9.3.3 Management review outputs

The outputs of the management review shall include decisions and action related to:

a) Opportunities for improvement
b) Any needs for changes to the QMS
c) resource needs

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

100

CLAUSE 10
IMPROVEMENT

101

10.1 Improvement

The organization shall determine and select opportunities for improvement and implement necessary actions to meet customer requirements and enhance customer satisfaction. This shall include, as appropriate:

- Improving processes to prevent nonconformities
- Improving products and services to meet known and predicted requirements
- Improving quality management system results

Note: Improvement can be affected reactively (corrective action), incrementally (continual improvement), by step change (breakthrough), creatively (innovation) or by re-organizing (transformation)

102

10.2 Nonconformity and Corrective Action

When nonconformity 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 by:
   1) reviewing 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
e) Update risk and opportunities
f) Make changes to the QMS

103

10.3 Continual Improvement

- Shall continually improve the suitability, adequacy and effectiveness of the QMS.
- Shall consider the results of the analysis and evaluation and the output from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

104

Requirements Deleted

- Several requirements in the current ISO 9001:2008 remain absent in ISO/DIS 9001 including:
  - **Quality Manual and procedures**
  - **Management Representative**
  - **Preventive Action**

105

THANK YOU

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