



WHAT IS QUALITY?

A usual answer to quality:

- Commitment to excellence
- Attention to details
- Doing things right
- Common sense
- Meeting customer requirements



KUALITI

Duran "Kesesuaian penggunaan" (Fitness for use)

Ishikawa Kepuasan Pelanggan

Crosby Menuruti Keperluan

Deming

Memenuhi keperluan pelanggan secara berterusan

Thomas H. Barry

Memenuhi keperluan dan harapan pelanggan secara berpatutan

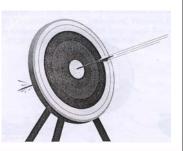
"Darjah Kecemerlangan" (The degree of excellence) The Oxford Dictionary:

WHAT IS QUALITY? (con't)

ISO DEFINITION:

'Ability of a set of inherent characteristics of a product, system or process to fulfil requirements of customers and other interest parties'

Quality must be in customer terms. The judgements of quality will lies on how well their needs and expectations are satisfied.



WHAT IS QUALITY? (con't)

In brief, quality can be sum of:

- Knowing the customers needs
- Designing to meet them
- Faultless construction
- Reliable bought-in components and sub-assemblies
- Certified performance and safety
- Clear instruction manuals
- Suitable packaging
- Punctual delivery
- Efficient back-up service
- Feedback of field experience

These elements add up to fitness for purpose and value for money, in fact into ownership satisfaction that brings customers back to buy a company's product again and again



Over 350,000 companies world are registered to ISO 9000 The benefits they find include:

- Improved consistency of service and product performance
- Higher customer satisfaction levels.
- Improved customer perception
- Improved productivity and efficiency
- Cost reductions
- Improved communications, morale and job satisfaction
- Competitive advantage and increased marketing and sales
- opportunities.

Dun and Bradstreet findings:

- 85% of registered firms report external benefits
 - Higher perceived quality
 - Greater customer demand
- 95% report internal benefits
 - Greater employee awareness
 - Increased operational efficiency
 - Reduced scrap expense

CIRAS News Says:

- Cutting quality cost in half can increase profit more than a 10 percent increase in sales.
- ISO 9000 is the most promising method for cutting the cost of quality.

A Case Study:

- Published in the Dallas Business Journal, August 18, 1997 the study credited ISO 9000 for:
 - Increased Productivity
 - Reduced scrap and waste
 - Record sales level
 - Catching inferior raw materials before they were used
 - A contract with Romania's state owned oil company.

Other Case Studies showed:

ISO Registration resulted in:

- 30% Reduction in customer claims
- 95% improvement in delivery time
- Reduced defects from 3% to 0.5%
- 40% reduction in product cycle time.
- 20% increase in on-time delivery
- International acceptance and recognition
- Facilitated trade in international markets
- Promoting of safety, reliability and quality in food products.

Registered companies site the benefits of ISO 9000 Registration as:

- Improved management
 - 86% of respondents
- Better customer service
 - 73% of respondents
- Improved efficiency
 - 69% of respondents
- Reduced waste
 - 53% of respondents
- Improved staff motivation
 - 50% of respondents
- Reduced costs
 - 40% of respondents

Irwin Professional Publishing survey results show:

- 30% Of registered companies experience increased customer demand.
- 50% Of registered companies have decreased number of customer audits.
- 69% Of registered companies have a competitive advantage in their market.
- 83% Of registered companies products have higher perceived quality in the marketplace.





KESAN ISO 9001 KE ATAS FAKULTI

- Memudahkan staf/penanggung tugas baru mempelajari dan menyesuaikan diri dengan kerja kerja yang perlu dilakukan
- Meningkatkan dan mempermudahkan 'ownership' sesuatu tugas/kerja
- Dapat membantu staf untuk saling ingat mengingatkan di antara satu sama lain
- Perbincangan sihat antara staf lama dan baru
- Menimbulkan minat staf untuk meningkatkan ilmu khususnya dalam pengurusan kualiti
- Secara keseluruhanya staf akademik merasa bertanggungjawab ke atas imej Fakulti

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KESAN ISO 9001 KE ATAS FAKULTI

- Staf jelas tentang proses kerja yang terlibat dan tanggungjawab masing masing
- Mudah untuk mencari punca sesuatu masalah jika terdapat ketidak lancaran sistem kerja
- Memberi peluang kepada staf untuk berinteraksi secara positif
- Memberi peluang staf mengenali jabatan lain dari segi amalan kerja yang selama ini dipraktikkan
- Memberi kesedaran kepada jabatan tentang kelemahan yang perlu diperbaiki
- Mudah untuk memperbaiki sistem kerja yang ada- pembaikan berterusan. Ada titik permulaan
- Staf merasa bertanggungjawab untuk turut memperbaiki sistem

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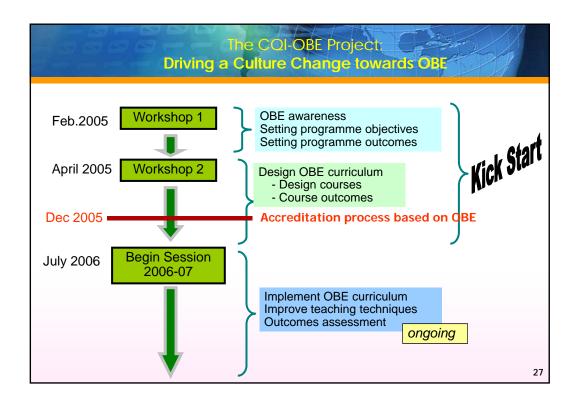








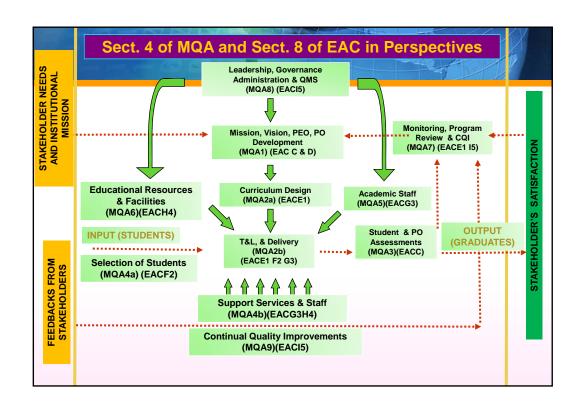


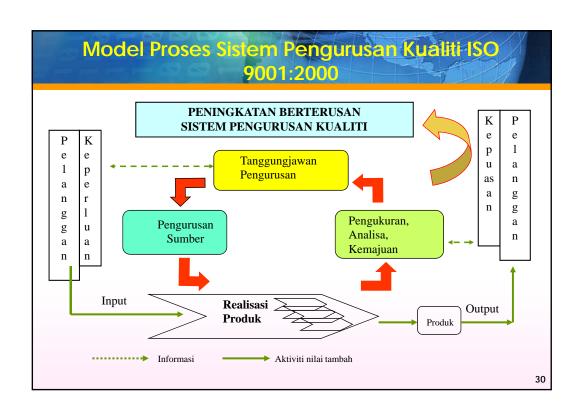


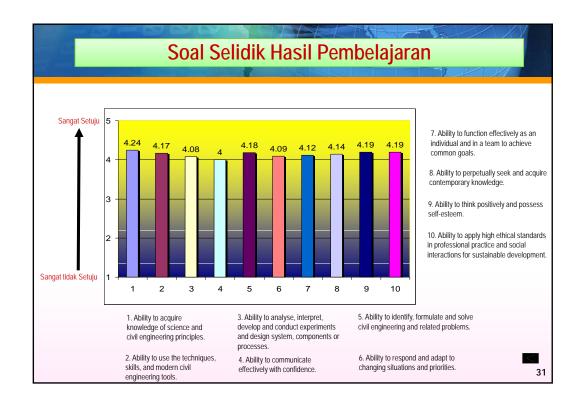
CURRENT STATUS

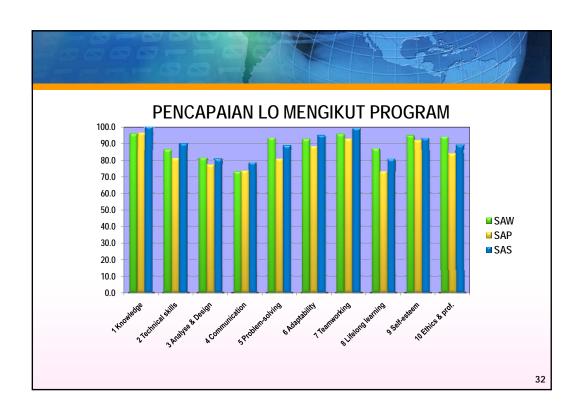
- 21/23 Engineering Programme undergone rigorous accreditation exercise by BEM mentored by 3 Washington Accord panels (USA, Australia and Hong Kong)
- based on EAC New Manual (2005)
- all programmes obtained full accreditation for 5 years

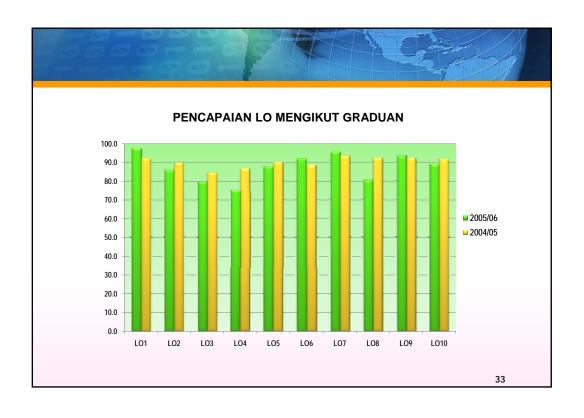
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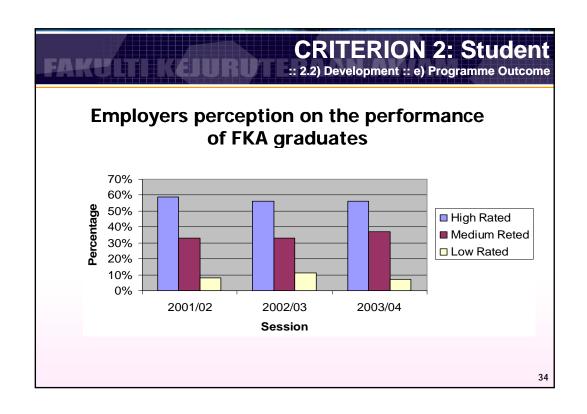


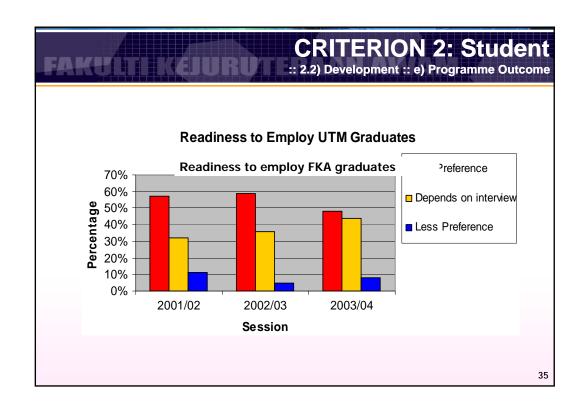


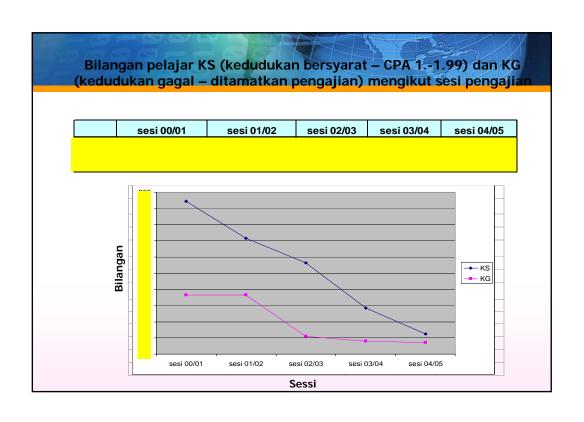


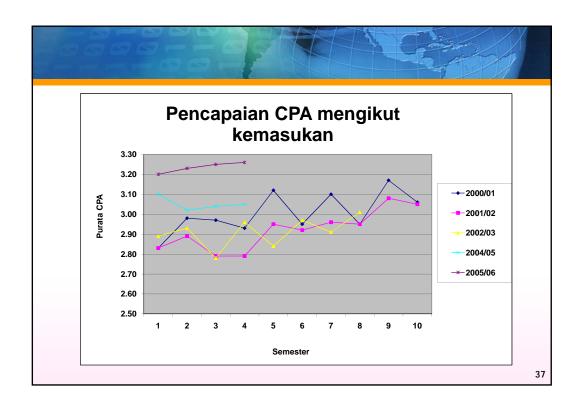


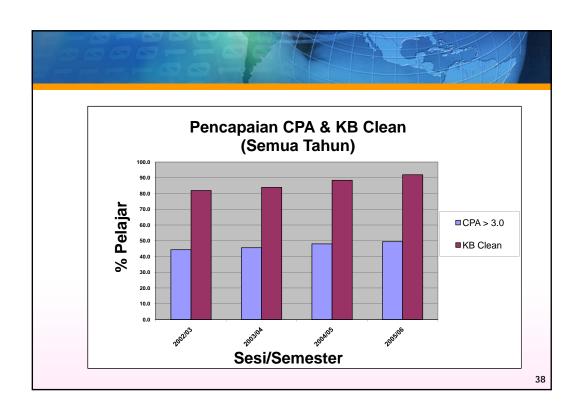


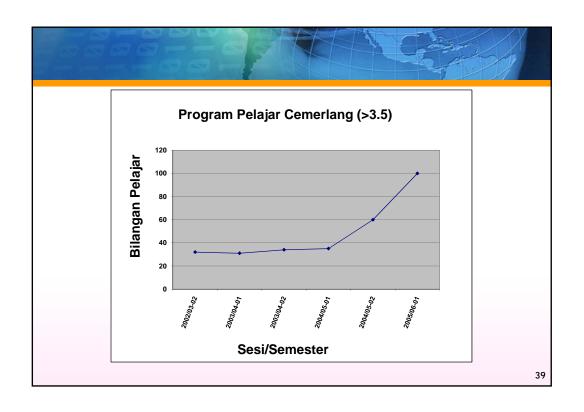


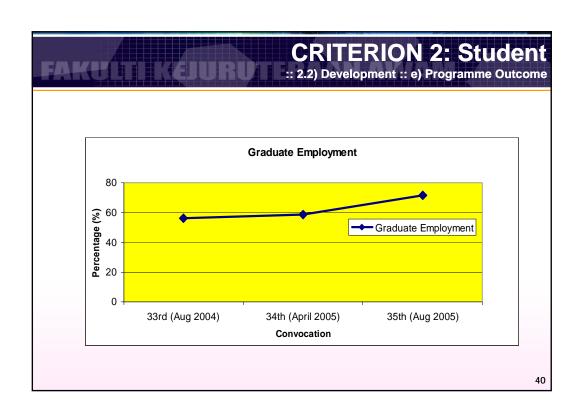


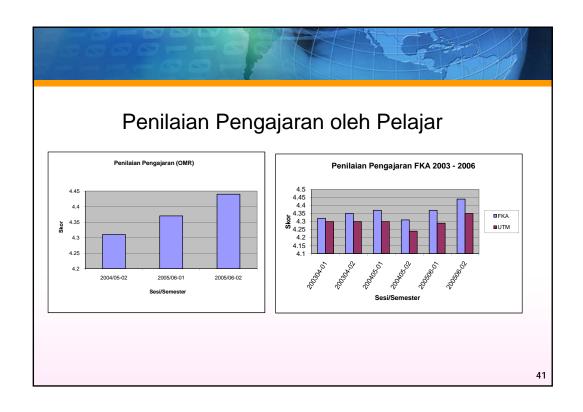




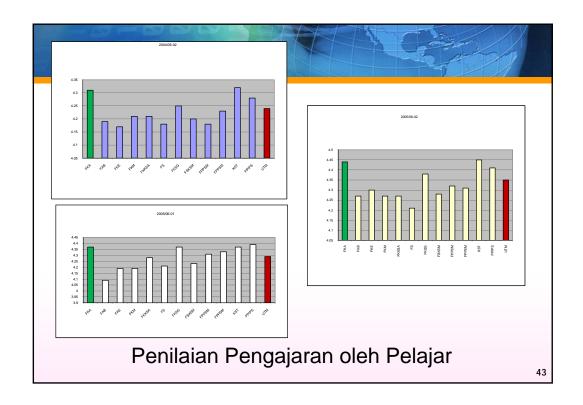


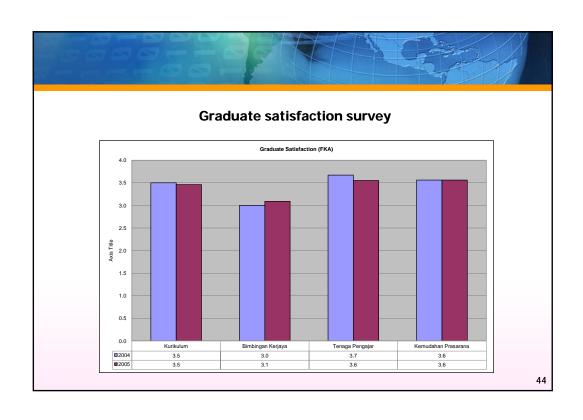


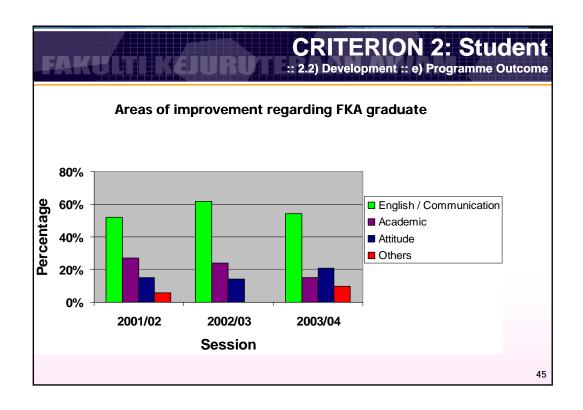


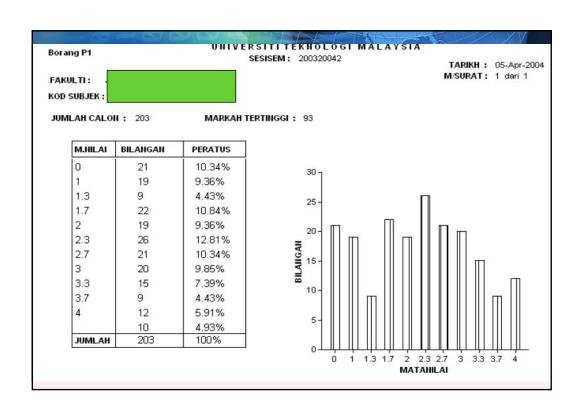


















Our Vision

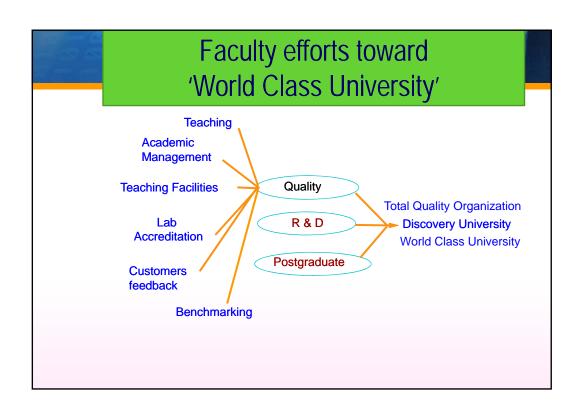
To be a World Class Professional Educational And Research Centre

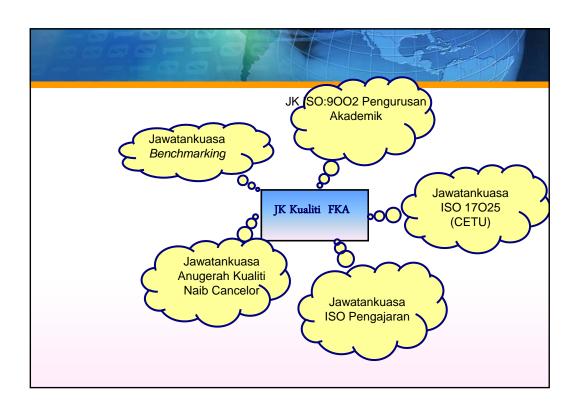
Our Mission

Leading Academic Excellence and Technological Development through Creativity

Our Motto

Always Ahead







ISO 9001:2000 (Pengurusan Akademik dan Pengajaran)

- Mengapa ISO 9001:2000
- Kesan perlaksanaan
- Kandungan ISO FKA
- Proses ke arah Persijilan
- Tanggung jawab Pengurusan
- Pengurusan Sistem Dokumentasi

Managana ICO 0004,20002

Mengapa ISO 9001:2000?

- Penerusan usaha yang sebelumnya
- ISO 9002 Pengurusan Akademik akan tamat pada 2003 dan keperluan ISO 9001:2000
- Persediaan Jaminan Kualiti Kementerian Pendidikan Malaysia dan EAC-BEM
- Kesungguhan UTM Perlantikan Dekan Pengajaran dan Pembelajaran
- Portfolio Pengajaran
- Persediaan bertemu Dr CT Morley (our external examiner from Cambridge Univ)

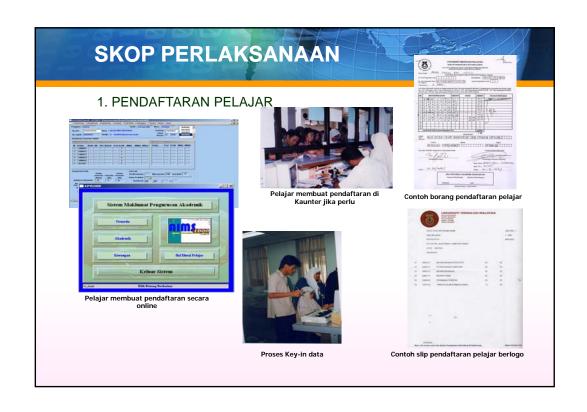
ISO 9001: 2000 (Pengajaran dan Pengurusan Akademik)

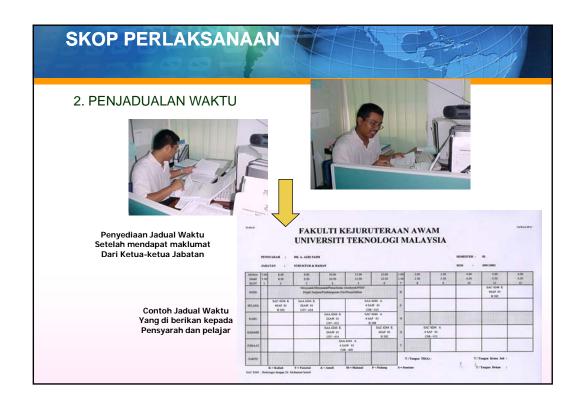
- Skop <u>lihat pelan proses</u>
- Kandungan dokumen ISO
 - Manual Kualiti
 - Prosidur Kualiti
 - Enam Prosedur Mandotari
 - Enam Prosedur Tambahan
 - Prosedur Kualiti Pengajaran
 - Prosedur Kualiti Jadual Waktu
 - Prosedur Kualiti Pendaftaran
 - Prosedur Kualiti Peperiksaan
 - Prosedur R/B dan Semakan Kurikulum
 - Prosedur Pengendalian sumber manusia
 - Arahan Kerja
 - Dokumen Sokongan rekod kualiti

Proses ke arah Persijilan ISO

- Awareness
- Kursus
- Penyediaan Dokumen
- Pengamalan Dokumen
- Audit
 - Jabatan
 - Dalaman
 - Pematuhan SIRIM
- Persijilan













WHAT IS ISO 9001:2000?

ISO 9001:2000 is a SYSTEM STANDARD, which describes and defines the basic elements of the quality system needed to ensure that an organization's product/services meet or exceed customer needs and expectations.

WHAT IS ISO 9000? (con't)

In the service sector, quality service that is capable of meeting the needs of the customer would include features such as timelines, accuracy, politeness, reliability, informativeness and availability.

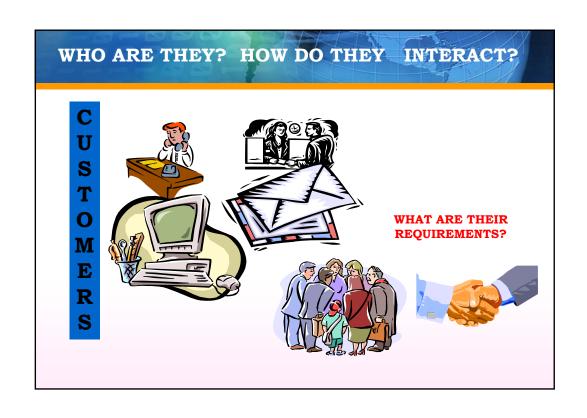
THE QUALITY MANAGEMENT PRINCIPLES

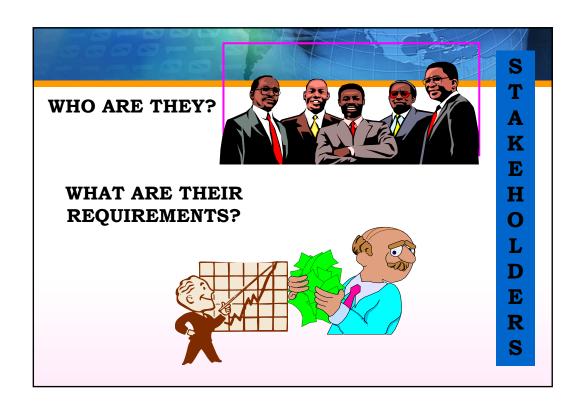
- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships.

Q U A L I T

WHO ARE THE CUSTOMERS AND STAKEHOLDERS OF FKASA?

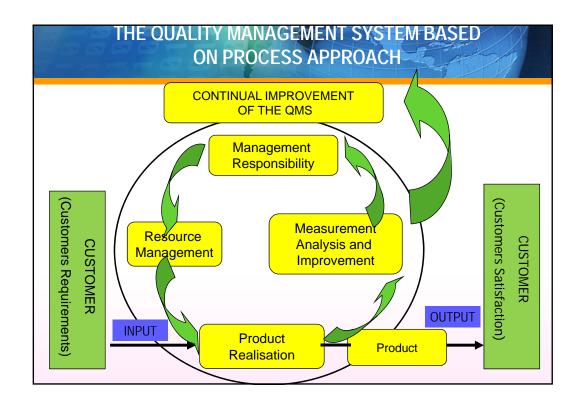


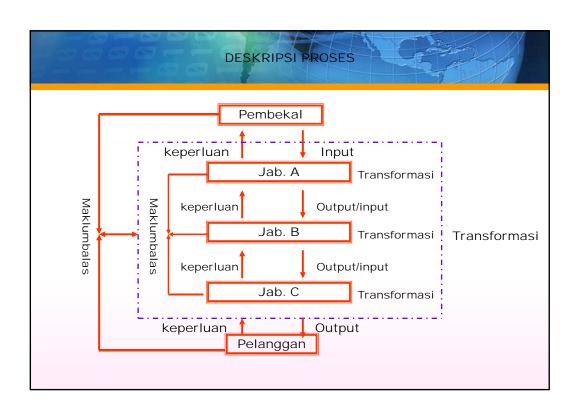


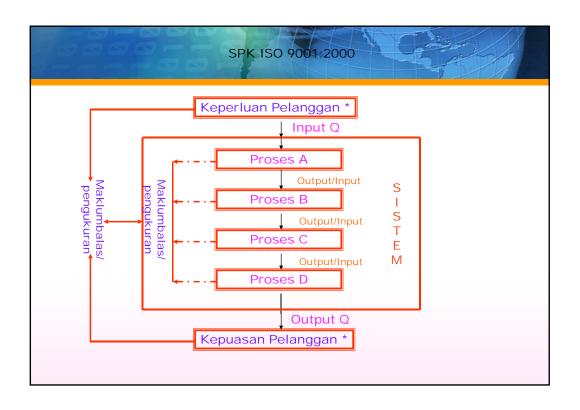








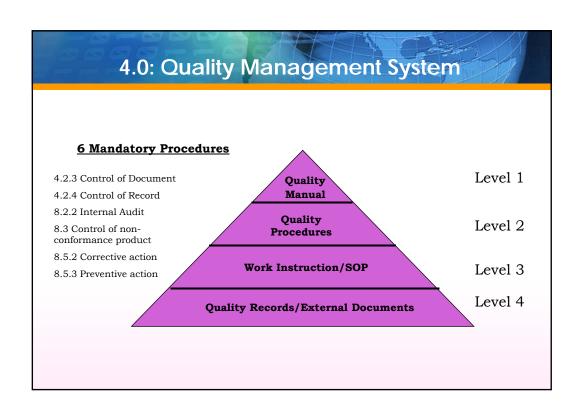




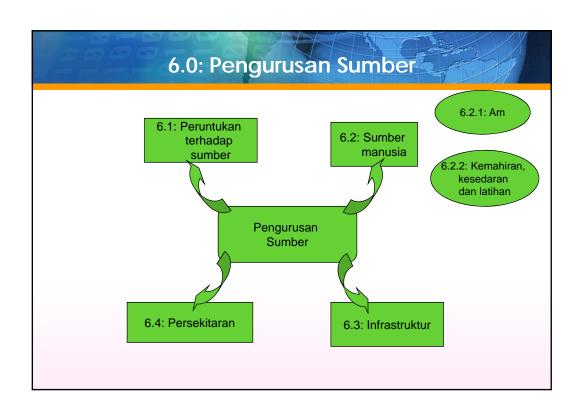
STRUCTURE of ISO 9001: 2000 REQUIREMENTS

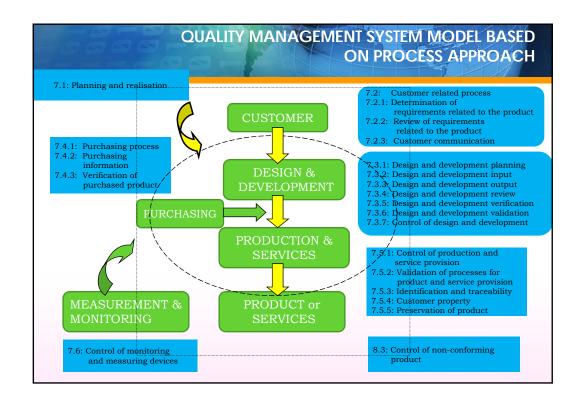
- SECTION 1: Scope
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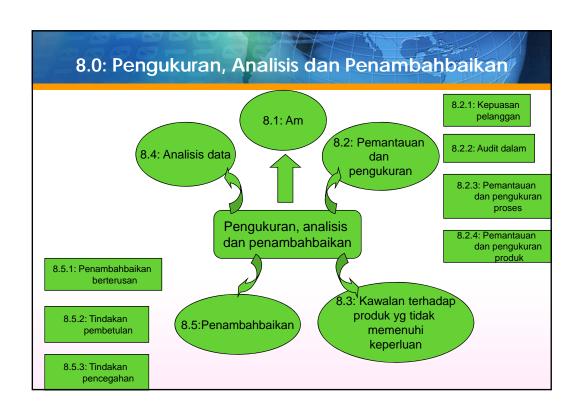














To the management

Commitment from the top management

- Managers: Get in first by learning about ISO
- Commit to the project, and make your commitment visible
- Plan and assign responsibilities
- Provide resources and trainings
- Reward ..reward.. and reward them

Management has prepared the way, and yet many still don't want to dive in..

To the management

- People won't want to get in on the project unless they know what it means to them and to their job.
 - Explain why ISO is important to the company
 - Explain how it will make their job easier.
 - Explain how their job will be different
 - And how it will be the same.
 - If I document everything I do, will I still have value?
 - What is this corrective action? It sounds like going to the principals office.
 - Someone is going to audit my work?

To the management

- Involve employees in the development process.
 - To modify or develop processes to meet the standard use the people that are currently involved in the process.
 - Train all staff on the corrective action and internal audits; emphasize the focus on improving the process.
- A general introduction to ISO 9000 is necessary for all staff.
- Consider more advanced training for the ISO committee member and other people driving the process.

Misinterpretation of the Standard

- Leads to wasted efforts and time.
 - Having to redesign processes numerous times.
 - Over Implementing the standard requiring too much in your system.
 - Uncovering major nonconformances during your audit, delaying your registration.

Avoid Drowning in Detail....

"The purpose of this procedure is to document the aforementioned activities, herin after referred to as the prescribed tasks in terms that preclude their execution in an inconsistent manner, wherin such inconsistency may potentially result in the prescribed tasks delivering a result that is not repeatable or reproducible"

And poorly written procedures

- Why use ten words when one will do?
 - "The items hereinunder referenced in some cases fell excessively outside normal parameters."
 - "The procedures contained herin are applicable to all operations in the following departments within their functional ambit"

Make procedures user friendly

- Use short sentences starting with a verb.
- Avoid using the passive voice. Make it clear who is performing the task.
- Use white space for easy reading.

Documentation Too Much? Too Little?

- Too Much:
 - Work instructions written for virtually everything
 - Overlap and repetition Including a process in more than one work instruction.
- Too little:
 - Lack of work instructions resulting in inconsistent processes and quality of the product.

Documentation

Lifesaving Technique

- Remember that the goal here is consistency for your processes.
- If two trained employees were to perform this task, would they do it the same way?
- If the answer to this is "Maybe not" a work instruction is appropriate.

Help them see how the procedure can work for them.

- It is important to demonstrate to these departments that the process should be consistent.
- The creativity takes place within the process.
- Document the procedure to describe the steps that must be followed, but not to prescribe the detail of their job.

Use a steering team

- Have decision makers and resource providers on the team.
- The team must:
 - Monitor the timeline
 - Remove obstacles
 - Provide resources
 - Coordinate efforts between different groups

Keep Employees aware of progress

- As the project goes on, keep employees informed
 - Employees must be aware of new processes.
 - Keep up visibility of the implementation
 - Newsletters, meetings, bulletin boards and other communication tools make all the difference in employee participation and awareness

Celebrate

- Involve employees and keep the project visible by celebrating progress and success.
 - Get togethers
 - Food
 - Employee recognition

Be prepared for your audit:

- Complete one cycle of internal audits.
- Complete one management review.
- Have approximately 3 months of records.
- Have a minimum of one design project documented start to finish.
- Make all employees aware of the audit.
- Let them know what to expect.
- Do a "Sweep" of your facility for uncalibrated equipment and uncontrolled documents.

Workout

- Use the system that you have built.
- Implement corrective actions.
- Emphasize the importance of
 - Corrective Action
 - Management Review
 - Internal Audits
- Continue training.

Never swim alone

- The system cannot be the responsibility of one person.
 - Assign responsibilities to a variety of people
 Don't assume that the Quality Manager has to be responsible for everything.
 - Use others as coordinators for Corrective action, Training Records, Equipment, Quality Records and Internal Audits.

Follow the Rules

- Keep the water warm
- Management must get in first
- Provide swimming lessons
- Use a coach
- Make procedures user friendly
- Use a steering team
- Celebrate and communicate
- Involve the people performing the process
- Watch out for the usual nonconformances
- Prepare for your audit

WALAUPUN TANGGUNGJAWAB MEMBANGUN,
MELAKSANA DAN MEMANTAU SISTEM PENGURUSAN
KUALITI ISO 9000 TERLETAK SEBAHAGIAN BESARNYA
DIBAHU PENGURUSAN ATASAN, NAMUN KOMITMEN DAN
KERJASAMA YANG PENUH DARI SEMUA STAF ADALAH
RESEPI YG PALING UTAMA DALAM MENGEKALKAN
KEUTUHAN DAN KESINAMBUNGAN SISTEM YANG
DIWUJUDKAN.

Hasbullah



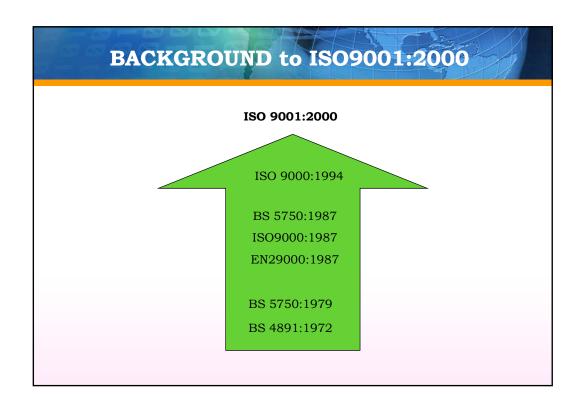


WHAT IS ISO 9001:2000?

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WHAT IS ISO 9000? (con't)

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ISO 9000:2000: FAMILY

ISO 9000:2000 : QUALITY MANAGEMENT SYSTEM - Fundamentals and vocabulary

Describes fundamentals of QMSs and specifies the terminology for QMSs.

ISO 9000:2000 : FAMILY (con't)

ISO 9001:2000 : QUALITY MANAGEMENT SYSTEM - Requirements

Specifies the requirements for QMSs for use where an organisation's capability to provide products that meet customer and applicable regulatory and statutory requirements needs to be demonstrated

ISO 9000:2000 : FAMILY (con't)

ISO 9004:2000 : QUALITY MANAGEMENT SYSTEM - Guidelines for Performance Improvement

Provides guidance on QMSs, including the processes for continual improvement that will contribute to the satisfaction of an organisation's customers and other parties

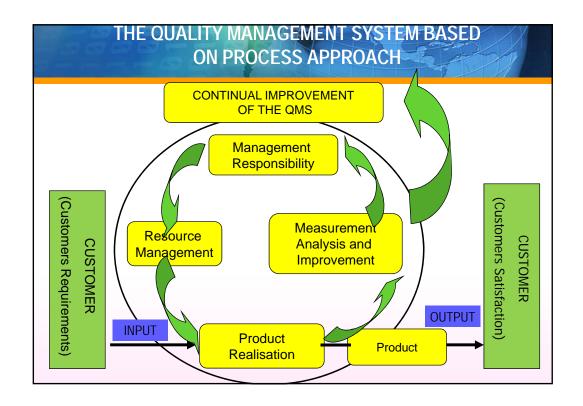
ISO 9000:2000 : FAMILY (con't)

■ ISO 19011: Guidelines on Auditing Quality and Environmental Management System

Provide guidance on managing and conducting environmental and quality audits.

THE QUALITY MANAGEMENT PRINCIPLES

- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships.



THE MAIN CLAUSES IN ISO 9001:2000?

STRUCTURE of ISO 9001: 2000 REQUIREMENTS

- SECTION 1: Scope
- SECTION 2 : Normative Reference
- SECTION 3 : Term and Definition
- SECTION 4 : Quality Management System
- SECTION 5 : Management Responsibility
- SECTION 6 : Resource Management
- SECTION 7 : Product Realisation
- SECTION 8 : Measurement, Analysis and Improvement

MS ISO 9001:2000 1. SCOPE

Clause 1.1 General

The international Standard specifies requirements for a QMS where an organisation

Needs to demonstrate its ability to consistently meets customer and applicable regulatory requirements

Aims to enhance customer satisfaction through:

- effectiveness application of the system, including processes for continual improvement of the system
- conformity to customer and applicable regulatory requirements



MS ISO 9001:2000 1. SCOPE (con't)

Clause 1.2 : Application
• A GENERIC international standard requirements applicable to all organisation



◆ Considerations for international standard requirements EXCLUSION if cannot be applied to the organisation

MS ISO 9001:2000 1. SCOPE (con't)

Exclusions are limited to requirements within clause 7
Do not affect the organisation's ability or responsibility to provide;

- ◆ product that meets customer requirements
- ◆ applicable regulatory requirements

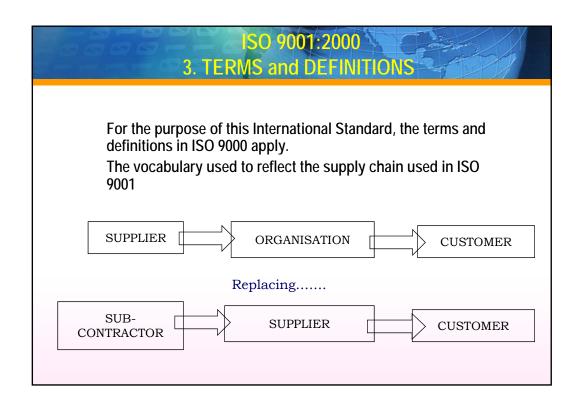
MS ISO 9001:2000 2. NORMATIVE REFERENCE

Reference made to the latest edition of;

ISO 9000: 2000

Quality Management System – Fundamentals and Vocabulary







MS ISO 9001:2000 5. MANAGEMENT RESPONSIBILITY

Requirements in brief:

- Top management is required to show its
 - commitment to the development and implementation of QMS and continually improve its effectiveness.
 - Focus on customer.
 - Establish Quality Policy, Quality Objectives, Quality Planning



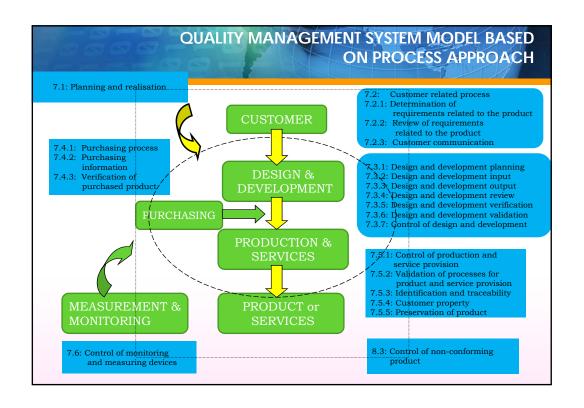
Requirements in brief:

- Determine and provide resources need to implement and maintain QMS, continually improve its effectiveness and enhance customer satisfaction
- This include providing competence personnel, appropriate infrastructure and conducive environment

MS ISO 9001:2000 7. PRODUCT REALIZATION

Requirements in brief

Plan and develop the processes needed for product realisation.



MS ISO 9001:2000 4. QUALITY MANAGEMENT SYSTEM (con't)

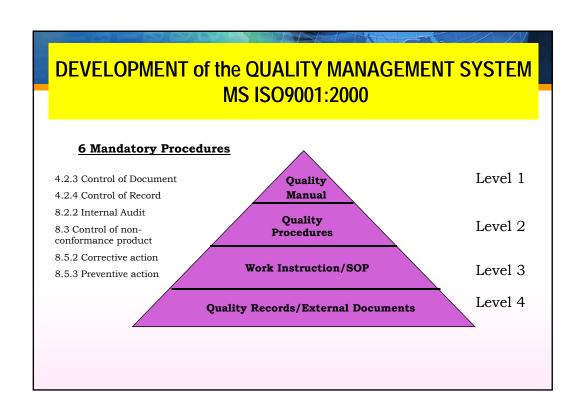
- Documentation required
 - quality manual
 - Procedures
 - records
- Control of documents and records



MS ISO 9001:2000 4. QUALITY MANAGEMENT SYSTEM (con't)

QMS Requirement Structure:

- 4.1 General requirements
- 4.2 Documentation requirements
 - 4.2.1 : General
 - 4.2.2 : Quality Manual
 - 4.2.3 : Control of Documents
 - 4.2.4 : Control of Records



QUALITY MANAGEMENT SYSTEM (con't) 4.1: General Requirements

- Identify the processes and determine the sequence, and interaction needed for the QMS and their application throughout the organisation.
- Determine criteria and methods to ensure effective operations and control of the processes.
- Ensure availability of resources and information to support operation and monitoring.

QUALITY MANAGEMENT SYSTEM (con't) 4.1: General Requirements

- Monitor, measure and analyse the processes
- Implement actions to achieve what was planned and continual improvement of the processes
- Processes managed in accordance with the requirement of this standard
- Control outsource activities

QUALITY MANAGEMENT SYSTEM (con't) 4.2: Documentation Requirements

4.2.1: General

QMS documentation include:

- statement of quality policy and quality objectives (refer 4.2.2 & 5.4.1)
- quality manual (refer 4.2.2)
- documented procedures required by the standard
- documents to ensure effective planning, operation and control of processes
- records (refer 4.2.4)

QUALITY MANAGEMENT SYSTEM (con't) 4.2: Documentation Requirements

4.2.2: Quality Manual

Establish and maintain quality manual that includes

- scope of QMS, including justification for exclusions
- documented procedures established for the QMS or reference to them
- description of the interaction between processes of the QMS

QUALITY MANAGEMENT SYSTEM (con't) 4.2: Documentation Requirements

4.2.3: Control of Documents

Established procedure to exercise control by:

- approving documents by the responsible personnel prior to issue
- review, update and re-approve documents
- changes and current revision status are identified

QUALITY MANAGEMENT SYSTEM (con't) 4.2: Documentation Requirements

- relevant versions of applicable documents available at point of use.
- documents remain legible and readily identifiable.
- external origin documents are identified and distribution controlled.
- prevent unintended use of obsolete documents and apply suitable identification if it is to be retained

QUALITY MANAGEMENT SYSTEM (con't) 4.2: Documentation Requirements

- 4.2.4: Control of Records
 - Establish and maintain record.
 - remain legible.
 - readily identifiable.
 - Retrievable.
 - documented procedures required for identification, storage, protection, retrieval, retention time and disposition

MS ISO 9001:2000 5. MANAGEMENT RESPONSIBILITY (con't)

- Define responsibility and authority.
- Appoint management representative.
- Establish communication within the organisation.
- Conduct management review meeting

MS ISO 9001:2000 5. MANAGEMENT RESPONSIBILITY (con't)

QMS Requirement Structure:

- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
 - 5.4.1 Quality Objectives
 - 5.4.2 Quality Management System Planning

MS ISO 9001:2000 5. MANAGEMENT RESPONSIBILITY (con't)

5.5: Responsibility, Authority and Communication

5.5.1: Responsibility and authority.

5.5.2: Management representative.

5.5.3: Internal communication

5.6: Management Review

5.6.1: General

5.6.2: Review input

5.6.3: Review output

MANAGEMENT RESPONSIBILITY (con't) 5.1 Management Commitment

- Top management to provide evident of their commitment through;
 - Communicating to the organisation the importance of meeting customer, statutory and regulatory requirements.
 - Establish quality policy.
 - Ensure quality objectives established.
 - Conduct management review meeting
 - Ensure availability of resources

MANAGEMENT RESPONSIBILITY (con't) 5.2 Customer Focus

- Ensure customer requirements are determined.
- Ensure customer requirements are met to enhanced customer satisfaction

MANAGEMENT RESPONSIBILITY (con't) 5.3 Quality Policy

- Ensure Quality Policy
 - Appropriate to the purpose of the organisation.
 - Includes commitment to comply with requirements and continually improve the effectiveness of QMS.
 - Provide framework for establishing and reviewing quality objectives.
 - Communicate and understood.
 - Reviewed for suitability

MANAGEMENT RESPONSIBILITY (con't) 5.4 Planning

- 5.4.1: Quality Objectives
 - Ensure quality objectives are established at relevant functions and levels.
 - Measurable and consistent with the quality policy
- 5.4.2: Quality Management System Planning
 - Ensure QMS planning is carried out to meet requirements (4.1) and quality objectives.
 - Integrity of QMS maintained even if changes are made

MANAGEMENT RESPONSIBILITY (con't) 5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Ensure responsibilities and authorities are defined and communicated

5.5.2 Management Representative

 Appoint an MR within the management members who ensure QMS is established, implemented and maintained, report on the performance of QMS and promote awareness of customer requirements.

MANAGEMENT RESPONSIBILITY (con't) 5.5 Responsibility, Authority and Communication

5.5.3 Internal Communication

- Appropriate communication process established.
- Communication with regard the effectiveness of QMS

MANAGEMENT RESPONSIBILITY (con't) 5.6 Management Review

5.6.1: General

- review QMS at planned interval
- include assessing opportunities for improvement and need for changes to QMS including quality policy and objectives

MANAGEMENT RESPONSIBILITY (con't) 5.6 Management Review

5.6.2 Review Inputs

Include information on;

- Results of audits.
- Customer feedback
- Process performance and product conformity
- Status of corrective and preventive actions.
- Follow-up actions on previous MRM.
- Changes affecting QMS.
- Recommendations for improvement

MANAGEMENT RESPONSIBILITY (con't) 5.6 Management Review

5.6.3: Review Outputs

Include decisions and action related to

- Improvement of the QMS and processes effectiveness.
- Product improvement related to customer requirements.
- Resource needs

MS ISO 9001:2000 6. RESOURCE MANAGEMENT

QMS Requirement Structure

6.1: Provision of Resources

6.2: Human Resources

6.2.1: General

6.2.2: Competence, Awareness and Training

6.3: Infrastructure

6.4: Work Environment

RESOURCE MANAGEMENT (con't) 6.1 Provision of Resources

- Determine and provide resources needed
 - To implement and maintain QMS and continually improve its effectiveness
 - Enhance customer satisfaction by meeting customer requirements

RESOURCE MANAGEMENT (con't) 6.2 Human Resources

- 6.2.1: General
 - Personnel performing work affecting quality must be competence
- 6.2.2: Competence, Awareness and Training
 - Determine necessary competence of personnel.
 - Provide necessary training/action

RESOURCE MANAGEMENT (con't) 6.2 Human Resources

- Evaluate the effectiveness of the actions.
- Ensure personnel are aware of the relevance and importance of their activities and its contribution to achievement of quality objectives.
- Maintain appropriate records.

RESOURCE MANAGEMENT (con't) 6.3 Infrastructure

- Determine, provide and maintain infrastructure needed to achieve conformity include
 - building, work space and associated utilities
 - process equipment (hardware and software)
 - supporting services (e.g transport and communication)

RESOURCE MANAGEMENT (con't) 6.4 Work Environment

Determine and manage the work environment needed to achieve product conformity

MS ISO 9001:2000 7. PRODUCT REALIZATION (con't)

QMS Requirements Structure

- 7.1: Planning of Realisation Processes
- 7.2: Customer Related Process
 - 7.2.1 Determination of requirements related to the product
 - 7.2.2 Review of requirements related to the product
 - 7.2.3 Customer communication

MS ISO 9001:2000 7. PRODUCT REALIZATION (con't)

- 7.3: Design and Development
 - 7.3.1: Design and development planning
 - 7.3.2: Design and development input
 - 7.3.3: Design and development outputs
 - 7.3.4: Design and development review
 - 7.3.5: Design and development verification
 - 7.3.6: Design and development validation
 - 7.3.7: Control of design development changes

MS ISO 9001:2000 7. PRODUCT REALIZATION (con't)

7.4: Purchasing

- 7.4.1: Purchasing Process
- 7.4.2: Purchasing Information
- 7.4.3: Verification of Purchased Product

MS ISO 9001:2000 7. PRODUCT REALIZATION (con't)

- 7.5: Production and Service Production
 - 7.5.1: Control of Production and Service Provision
 - 7.5.2: Validation of Processes for Production and Service Provision
 - 7.5.3: Identification and Traceability
 - 7.5.4: Customer Property
 - 7.5.5: Preservation of Product
- 7.6: Control of Monitoring and Measuring Devices

PRODUCT REALIZATION (con't) 7.1: Planning of Realisation Process

- Plan and develop the processes needed for product realisation. This include objectives, processes, documentation, resources facilities, verification, validation, monitoring activities, inspection, and testing and
- The record required to provide evidence of outcome must be maintained

PRODUCT REALIZATION (con't) 7.2: Customer Related Processes

- 7.2.1:Determination of requirements related to the product
 - Determine requirements specified by the customer, requirements not stated by the customer but necessary for specified or intended use, statutory and regulatory requirements related to the product, and any additional requirements determined by the organisation

PRODUCT REALIZATION (con't) 7.2: Customer Related Processes

- 7.2.2: Review of requirements related to the product
 - Review and resolve before commitment to supply a product or service to a customer:
 - the product requirements.
 - variations between previously expressed and contract requirements.
 - the organisations ability to meet the defined requirements

PRODUCT REALIZATION (con't) 7.2: Customer Related Processes

- Records of the results of the review and actions arising from the review must be maintained.
- Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organisation before acceptance.

PRODUCT REALIZATION (con't) 7.2: Customer Related Processes

- 7.2.3: Customer Communication
 - The organisation shall determine and implement effective arrangements for communicating with customers in relation to product information, enquiries orders, amendments, customer feedback and complaints

- 7.3.1: Design and Development Planning
 - Plan and control the design/development of product. Planning includes determining: design stages, that review, verification and validation are appropriate and the responsibilities and authorities for design.

PRODUCT REALIZATION (con't) 7.3: Design and Development

- 7.3.2: Design and Development Inputs
 - Inputs relating to product requirements must be determine.
 - Record maintained.
 - This includes functional and performance requirements, applicable statutory and regulatory requirements, information derived from previous similar designs, and other requirements essential for design and development

- 7.3.3: Design and Development Outputs (Paperwork)
 - The outputs of design and development must be provided in a form that enables verification against the input and must be approved prior to release.
 - Outputs need to meet input requirements, provide information for purchasing and production, specify acceptance criteria and characteristics essential for safety and proper use.

PRODUCT REALIZATION (con't) 7.3: Design and Development

- 7.3.4: Design and Development Review
 - At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements to: identify the ability to meet requirements and to identify problems and propose necessary actions

- 7.3.5: Design and Development Verification
 - Verification must be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements

PRODUCT REALIZATION (con't) 7.3: Design and Development

- 7.3.6: Design and Development validation (product/service)
 - Design and dvelopment validation must be performed in accordance with planned arrangements to ensure thet the resulting product is capable of meeting requirements for specified application or intended use, where known.

- 7.3.7: Control of Design and/or Development Changes
 - Design and development changes must be identified and records maintained. Changes must be reviewed and records of the results and any necessary actions maintained

PRODUCT REALIZATION (con't) 7.4: Purchasing

- 7.4.1: Purchasing Control
 - The organisation shall: ensure that purchased product conforms to specified purchase requirements and evaluate and select suppliers based on their ability to supply product in accordance with the organiser's requirements. Criteria for selection, evaluation and re-evaluation shall be established

PRODUCT REALIZATION (con't) 7.4: Purchasing

- 7.4.2: Purchasing Information
 - Purchasing information must describe the product to be purchased, including where appropriate: requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel, and quality management system requirements

PRODUCT REALIZATION (con't) 7.4: Purchasing

7.4.3: Verification of Purchased Products

 The organisation must establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements including verification at supplier's premises

PRODUCT REALIZATION (con't) 7.5: Production and Service Provision

7.5.1: Control of Production and Service Provision

- The organisation must plan and carry out production and service provision under controlled conditions.
- This includes as applicable: availability of information that describes the characteristics of the product, work instructions, suitable equipment, the use of monitoring and measuring devices, the implementation of monitoring and measurement, and the implementation of release, delivery and post delivery activities.

PRODUCT REALIZATION (con't) 7.5: Production and Service Provision

7.5.2: Validation of Processes for Production and Service Provision

- The organisation must validate any processes for production and service proovision where the resulting output cannot be verified by subsequent monitoring or measurement.
- This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered

PRODUCT REALIZATION (con't) 7.5: Production and Service Provision

- 7.5.3: Identification and Traceability
 - Where appropriate, the organisation must identify the product by suitable means throughout product realisation.
 - This includes the product status with respect to monitoring and measurement requirements.
 - Where traceability is a requirement, the organisation must control and record the unique identification of the product

PRODUCT REALIZATION (con't) 7.5: Production and Service Provision

- 7.5.4: Customer Property
 - The organisation must exercise care with customer property while under the organisation's control or being used by the organisation.
 - It must identify, verify, protect and safeguard customer property provided for use or incorporation into the product.
 - If lost, damaged or otherwise found unsuitable for use, this must be reported to the customer and record maintained

PRODUCT REALIZATION (con't) 7.5: Production and Service Provision

- 7.5.5: Preservation of Product
 - The organisation must preserve the conformity of product during internal processing and delivery to the intended destination.
 - This includes identification, handling, packaging, storage and protection.
 - Preservation must also apply to the constituent parts of a product

PRODUCT REALIZATION (con't) 7.6: Control of Monitoring and Measuring Devices

- The organisation must determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product requirements be determined.
- It must establish processes to ensure that monitoring and measurement can be carried out and is carried out in the manner that is consistent with monitoring and measurement requirements.

PRODUCT REALIZATION (con't) 7.6: Control of Monitoring and Measuring Devices

- Where necessary to ensure valid results, measuring equipment must be calibrated or verified at specified intervals, or prior to use, against measurement standard traceable to international or national measurement standard.
- Where no such standard exist, the basis used for calibration or verification must be recorded.
- Measuring equipment must also be adjusted, readjusted, identified, safeguarded and protected

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.1: General

- The organisation must plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate or ensure product/service or system conformity and improvement.
- This include where applicable the need for methodologies including statistical techniques

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.2: Monitoring and Measurement

- 8.2.1: Customer satisfaction
 - As one of the measurements of the performance of the QMS, the organisation must monitor information relating to customer perception as to whether the organisation has fulfilled customer requirements.
 - The methods for obtaining and using this information must be determined

MEASUREMENT, ANALYSIS and IMPROVEMENT (con't) 8.2: Monitoring and Measurement

- 8.2.2: Internal Audit
 - The organisation must conduct internal audit at planned interval.
 - Audit programme must be prepared prior to audit based on status and importance of the process/area to be audited and result previous audit.
 - Audit criteria, method, scope and frequency must be defined.

MEASUREMENT, ANALYSIS and IMPROVEMENT (con't) 8.2: Monitoring and Measurement

- Selection of auditors and conduct of audits must ensure objectivity and impartiality. Auditors cannot audit their own work.
- Corrective action taken without undue delay.
- Record maintained

MEASUREMENT, ANALYSIS and IMPROVEMENT (con't) 8.2: Monitoring and Measurement

8.2.3: Monitoring and Measurement of Processes

- The organisation must apply suitable methods for monitoring and where applicable measurement of the QMS processes.
- These methods must demonstrate the ability of the processes to achieve planned results.
- When planned result is not achieved, correction and corrective action must be taken as appropriately

MEASUREMENT, ANALYSIS and IMPROVEMENT (con't) 8.2: Monitoring and Measurement

- 8.2.4: Monitoring and Measurement of Product
 - The organisation must monitor and measure the characteristics of the product to verify that product requirements have been met.
 - This must be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements.

MEASUREMENT, ANALYSIS and IMPROVEMENT (con't) 8.2: Monitoring and Measurement

- Evidence of conformity to acceptance criteria and records of persons authorising product release are required.
- Release must not proceed until planned arrangements are satisfactorily completed or otherwise approved by a relevant authority

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.3: Control of Non-Conforming Product

- The organisation must ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.
- The controls and related responsibilities and authorities for dealing with non-conforming product must be defined
- Option include eliminating the detected non-conformity, authorising its use release or acceptance under concession or precluding its use for original intended use or application.

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.4: Analysis of Data

- The organisation must determine, collect, analyse data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made.
- Data: customer satisfaction, product conformity, characteristics and trends of processes/products and suppliers

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.5: Improvement

8.5.1: Continual Improvement

 The organisation must continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.5: Improvement

8.5.2: Corrective Action

 The organisation must take action to eliminate the cause of non conformities in order to prevent recurrence. Corrective action must be appropriate to the effects of the nonconformities encountered.

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.5: Improvement

- A documented procedure must be established to define requirements for: reviewing non-conformities (including customer complaints), determining the causes of non-conformities, evaluating the need for action to ensure that non-conformities do not recur, determining and implementing action needed.
- Records of the results of action taken must be maintained

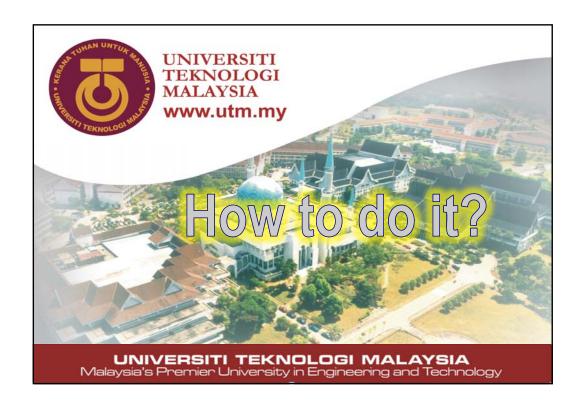
MEASUREMENT, ANALYSIS and IMPROVEMENT 8.5: Improvement

- 8.5.3: Preventive Action
 - The organisation must determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence
 - Preventive action must be appropriate to the effects of the potential problems.

MEASUREMENT, ANALYSIS and IMPROVEMENT 8.5: Improvement

- A documented procedure must be establish to define: requirements for: determining potential non-conformities and their causes, evaluation of the need for action to prevent occurrence of non-conformities, determining and implementing action needed
- records of results of action taken and reviewing preventive action taken must be maintained.





A Guide for Continuous Improvement (taken from the EAC Training Module)

- Who are your stakeholders?
- What are the services/outcomes you produce?
- Are your objectives/outcomes understood by your constituencies?
- What services, facilities, and policies must be present if you are to satisfy your
- Does your institutional leadership understand your needs?
- What steps do you perform to produce your services/outcomes?
- How do you measure your results?
- How do you use these measurements to continually improve the services you provide?
- Are you achieving your objectives/outcomes? Are you improving?
- Are your constituencies/stakeholders satisfied?

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Core Steps in Continuous Improvement

- Form a team that has knowledge of the system needing improvement.
- Define a clear aim.
- Understand the needs of the people who are served by the system.
- Identify and define measures of success.
- Brainstorm potential change strategies for producing improvement.
- Plan, collect, and use data for facilitating effective decision making.
- Apply the scientific method to test and refine changes.

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