

REPORT

Quality Management System Auditor/Lead Auditor Training Course

SPM STISI Telkom
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1. Pengenalan Quality Management System

- Quality is “Degree to which a set of inherent characteristics fulfils requirements”
- In ISO 9000:2005 Grade is inherent in the product and may be altered by changes in specification
- Why should an organization need a quality management system? Because we need to be as near to the centre as possible when aiming at the moving target we call quality
- How do you think that ISO 9001:2008 could help? “Karena mengingat bahwa ukuran kualitas setiap orang itu bervariasi maka harus ada satu ukuran kualitas yang diakui oleh setiap orang, yang paling mendekati ukuran kualitas dari setiap orang. Intinya harus, ada standar khusus” masuknya ke standar dalam ukuran dan bukan produk yang diukur tapi sistem.
- 8 Prinsip Quality Management System

1. Customer focus

Organizations depend on their customers, but never forget the other interested parties (stakeholders, Suppliers, Society, Employees)

2. Leadership

Leaders provide:

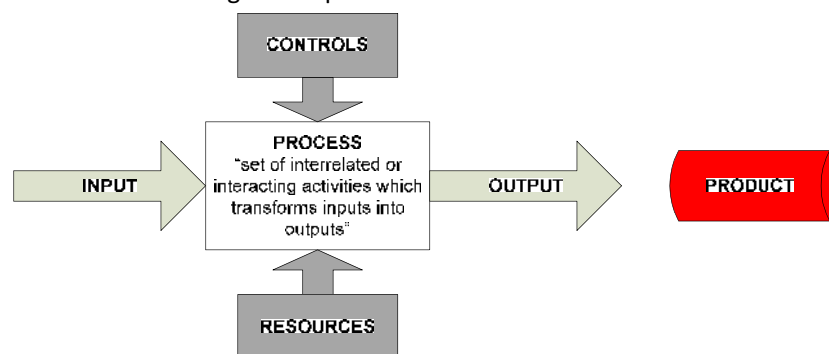
- Unity of purpose
- Direction
- Internal environment

3. Involvement of people

People are the essence of the organization. Their full involvement enables using their abilities to the benefit of the organization.

4. Process approach

A desired results is achieved more efficiently when activities and related resources are managed as a process



Process Effectiveness:

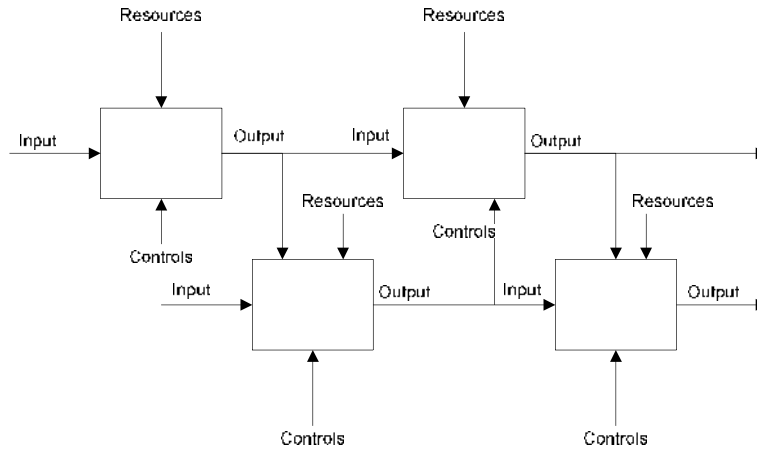
Extent to which planned activities are realized and planned results achieved

Process Efficiency:

Relationship between the results achieved and the resources used

5. System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its objectives



6. Continual improvement

The methodology known as “Plan-Do-Check-Act” can be applied to all processes of the QMS



A permanent objective of the organization

Plan: establish objectives and processes necessary to deliver results in accordance with customer requirements and the organizations policies

Do: implement the processes

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results

Act: take actions to continually improve process performance

7. Factual approach to decision making

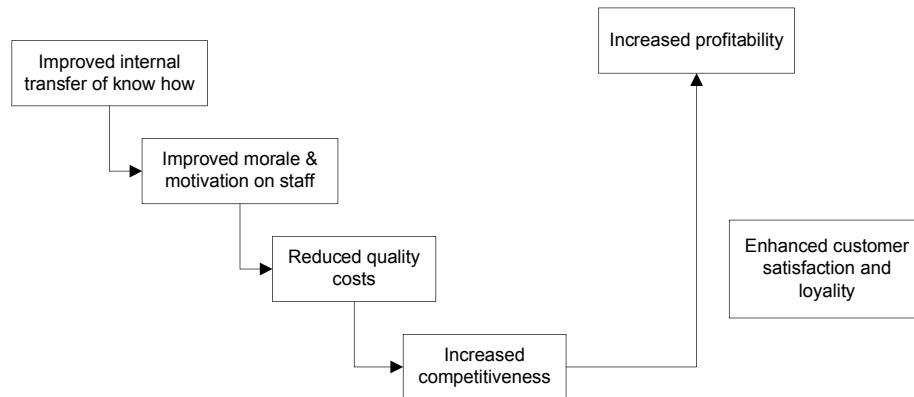
Effective decisions are based on the analysis of data and information

8. Mutual beneficial supplier relationships

An organization and its suppliers are interdependent

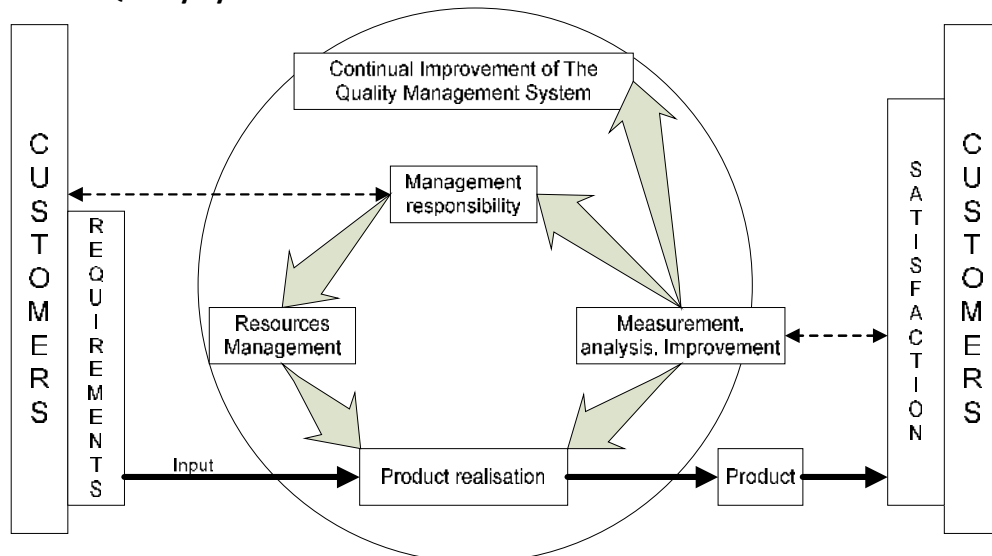
A mutually beneficial relationship enhances the ability of both to create value

Benefit of Quality Management System

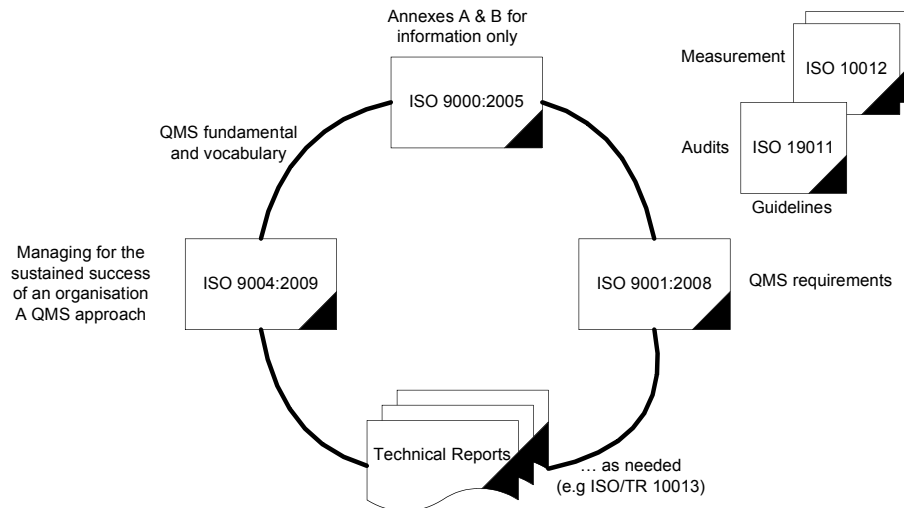


- Certification of quality system to ISO 9001 as a “bonus”:
- Tangible proof that the company’s quality system complies with internationally recognized standard
- Avoidance of multiple second party audits
- Marketing edge

Overall Quality System Model



2. Sekilas Tentang Iso 9001:2008 ISO 9000 Family



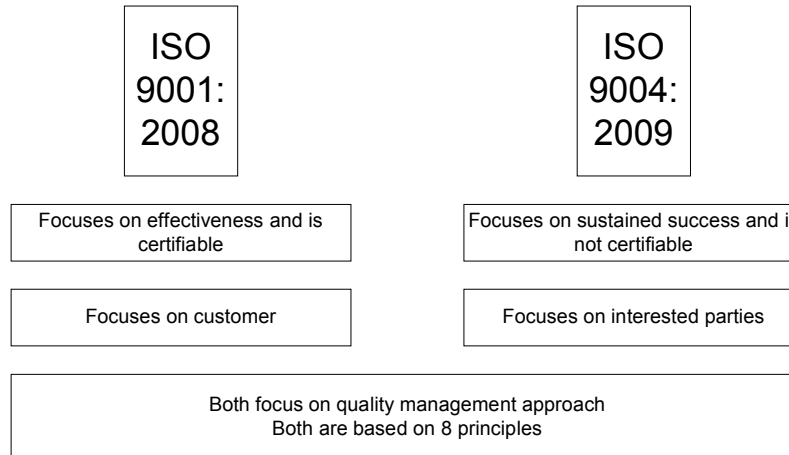
0.1 General

- Adoption of QMS, a strategic decision
- Many factors can influence the design of QMS
- Requirements of QMS are complementary to those of products
- Standard can be used by many parties

0.2 Process approach

- Process approach to quality management encouraged
- Introduces the process model as conceptual presentation of QMS requirements specified
- Name the parameters needed to identify a process...
- The advantage of this approach is that it permits ongoing control not only over the individual processes but also their interaction. This approach takes into account the importance of:
 - a. Understanding and meeting requirements
 - b. Considering processes in terms of added value
 - c. Obtaining results of their performance and effectiveness
 - d. Continually improving them based on objective measurement

0.3 Relationship with ISO 9004



Lingkup ISO 9001:2008

1. Scope

1.1. General

The standard specifies requirements for QMS for use to

- a. Needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory
- b. Aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements

1.2. Application

Requirements are generic

Requirement may be excluded if cannot be applied due to the nature of organization and its product

Exclusions must:

- Not affect ability or responsibility to provide conforming product
- Be limited to requirements in clause 7

Conformity to ISO 9001 may not be stated if exclusions go beyond above

2. Normative Reference

For dated references, only the edition cited applies

For undated references the latest edition applies

ISO 9000:2005 QMS – fundamentals and vocabulary

3. Terms & Definition

For terms & definitions, ISO 9000 applies

Throughout the standard the term “product” also means “service”

4. Quality Management System
 - 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

5. Management Responsibility
 - 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
 - 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

6. Resource Management
 - 6.1. Provision of resources
 - 6.2. Human resources
 - 6.2.1. General
 - 6.2.2. Competence, training and awareness
 - 6.3. Infrastructure
 - 6.4. Work environment

7. Product Realization
 - 7.1. Planning of product realization
 - 7.2. Customer-related processes
 - 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
 - 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 output

- 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 and development changes
- 7.4. Purchasing
 - 7.4.1. Purchasing process
 - 7.4.2. Purchasing information
 - 7.4.3. Verification of purchased product
- 7.5. Production and services provision
 - 7.5.1. Control of production and services 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 equipment

- 8. Measurement, Analysis, Improvement
 - 8.1. General
 - 8.2. Monitoring and measurement
 - 8.2.1. Customer satisfaction
 - 8.2.2. Internal audit
 - 8.2.3. Monitoring and measurement of processes
 - 8.2.4. Monitoring and measurement of product
 - 8.3. Control of nonconforming product
 - 8.4. Analysis of data
 - 8.5. Improvement
 - 8.5.1. Continual improvement
 - 8.5.2. Corrective action
 - 8.5.3. Preventive action

3. Dokumentasi

Document in ISO 9000:2005 is Information and supporting medium

Information:

- Procedure
- Specification
- Record
- Drawing
- Report
- Standard

Medium:

- Paper
- Magnetic
- Electronic
- Photographic
- Master sample
- Etc

Objective of documentation

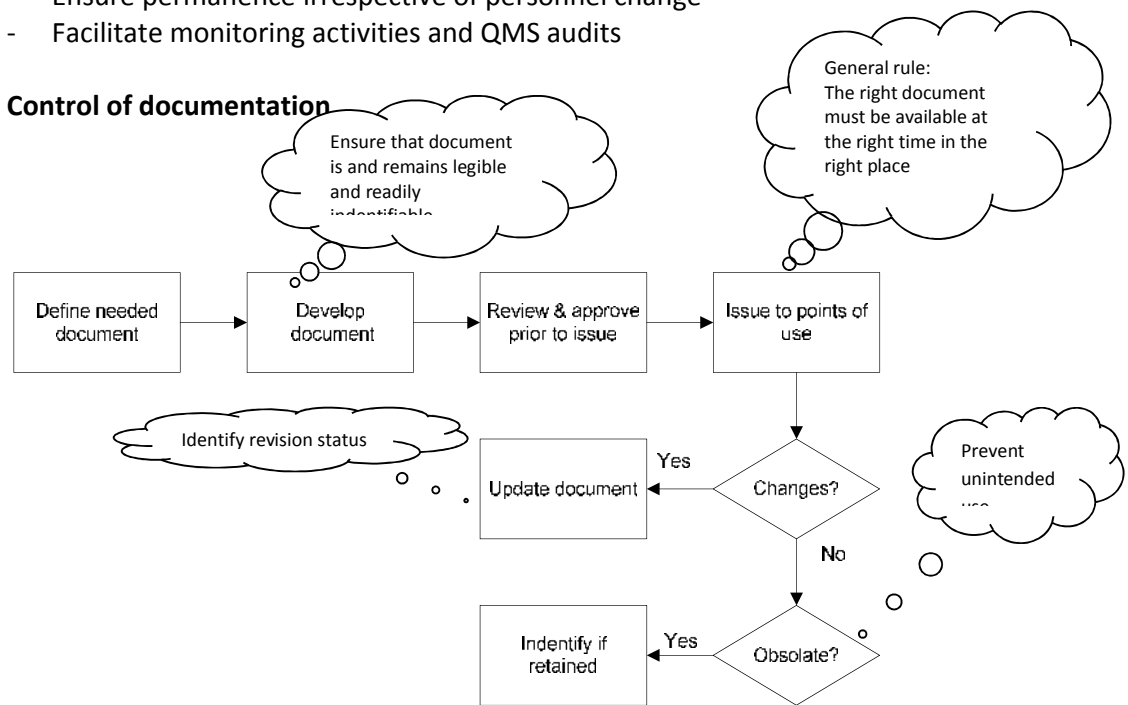
- Communicate information
 - Means to transmit and communicate information

- Type and amount depend on
 - Ⓜ Grade of formality of communication System
 - Ⓜ Level of communication skill
 - Ⓜ Organizational culture
 - Ⓜ Nature of product and process
- Evidence conformity
 Provide evidence that what has been planned has been achieved
- Share knowledge
 Disseminate and preserve the organizations know-how
 - Technical specification
 - Manufacturing technology

Function and value of documentation

- Provide concise set of requirements
- Facilitate consistency of quality activities
- Convey requirements simultaneously to all concerned
- Facilitate effective change control
- Ensure permanence irrespective of personnel change
- Facilitate monitoring activities and QMS audits

Control of documentation



Documentation structure

Typical Structure



Quality Objectives:

In clause 5.4.1, Quality objectives, requires objectives to be measurable.

When measuring objectives, we need three places of information:

1. The situation NOM
2. The situation we want to achieve
3. How long are we going to allow

SMART is useful system to use when setting and testing objectives:

S for Specific

M for measurable

A for Ambitious or achievable

R for realistic

T for Time frame or time bound

For example:

1. Objective: "Zero customer complain" (NOT SMART, because no time frame and no measurable)
2. Objective: "Market share to be increased: at present date, 10% to be increased to 15% after one year (SMART)

Quality Manual:

The Quality manual must included

- Scope of QMS, including detail and justification of exclusion
- Documented procedures for the QMS, or references to them
- Description of the interaction between processes of QMS

The quality manual could also included:

- A description of the organization
- The quality policy

- Global quality objectives
- The structure of the organization
- Main responsibilities and authorities
- A summary of the specific approach to compliance with the standard and other requirement

Purpose of the quality manual

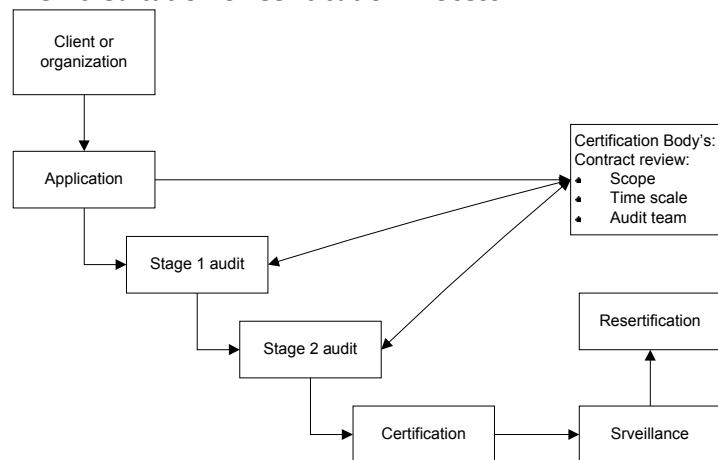
- Describing and implementing QMS
- Communicate requirements
- Basis for auditing
- Ensuring continuity
- Reduce learning curve
- Demonstrating compliance to the standard
- Prequalification and contractual purposes
- Good piece of sales literature

In ISO 9001:2008 requires the following “documented procedures”

1. Control of document (clause 4.2.3)
2. Control of record (clause 4.2.4)
3. Internal audit (clause (8.2.2)
4. Control of nonconforming product (8.3)
5. Corrective action (8.5.2)
6. Preventive action (8.5.3)

4. Proses Audit

The Accreditation or Certification Process



Stage 1 “Readiness audit”

- Recommended to be done on site
- Audit of documentation
- Evaluation of location
- Review of key performance parameter
- Validation of scope

- Collection of information regarding statutory and regulatory requirements and their compliance
- Review of allocation of resources for stage 2 audit, agree with client and plan for stage 2
- Evaluation of internal audit & management review
- Assess the overall readiness for stage 2 audit
- Report the findings including areas of concern to the client/auditee

Stage 2 Audit “Implementation” Audit

- The purpose: evaluation of implementation, including effectiveness, of the system
- Must be conducted at site
- Conformity to all requirement of the audit criteria
- Performance against objectives
- Performance against legal compliance
- Operational control of clients’ processes
- Internal auditing and management review results, actions and their effectiveness at locations
- Managements responsibility for their policies
- Linkages between statutory and regulatory requirements, quality policy, performance objectives and targets
- Evaluate systems effectiveness in:
 - Achieving objectives and targets
 - Implementing policy commitments
 - Operational controls in all areas of QMS
 - Corrective actions
- Evaluate the overall implementation and effectiveness of the organizations QMS
- Full system audit covers:
 - Every clause of ISO 9001 for: intent, implementation, and effectiveness
 - Linkages between elements of the QMS
- 3 Key question:
 1. Is the system adequate?
 2. Is the system suitable?
 3. Is the system affective?

Surveillance Audits

- Conducted at least once per year on site
- Covers all function/processes over a 3 year period subsequent to certification/ Re certification audit
- Audit plan based upon result of previous audits & importance & status of processes
- Internal audits may be taken into account

- Assess organizations continued conformance to the certified standard requirements
- What shall be checked during surveillance audits?

Audit Management

1. Initiating the audit
 - Define audit objectives, scope and criteria
 - Determine feasibility of the audit
 - Select the audit team
 - Establish initial contact with the auditee
 - Audit criteria: reference against which conformity is determined
 - Audit Scope: Extent and boundaries of the audit including
2. Conducting stage 1 audit
 - Adequacy of documentation
 - Assess readiness for full systems audit
 - Focus on planning for stage 2
 - Establish personal contact and report with auditee
 - Validates scope, purpose, methods
 - Gather additional information
 - Identify potential problems
3. Preparing for stage 2 audit
 - Validation of number of person-days
 - Preparation of audit plan
 - Preparation of working documentations
 - Keeping auditee advised, agreement on date and time
 - Logistic
4. Conducting on site audit activities
 - Conducting the opening meeting
 - Communication during the audit
 - Collecting and verifying information
 - Preparing audit conclusion
 - Conducting the closing meeting
5. Opening meeting agenda
 - Introduce the Team
 - Reason, scope & criteria
 - Review audit plan and methods
 - Explain about sampling
 - Confidentiality
 - Method of reporting
 - Grading of Not Conforming Report's

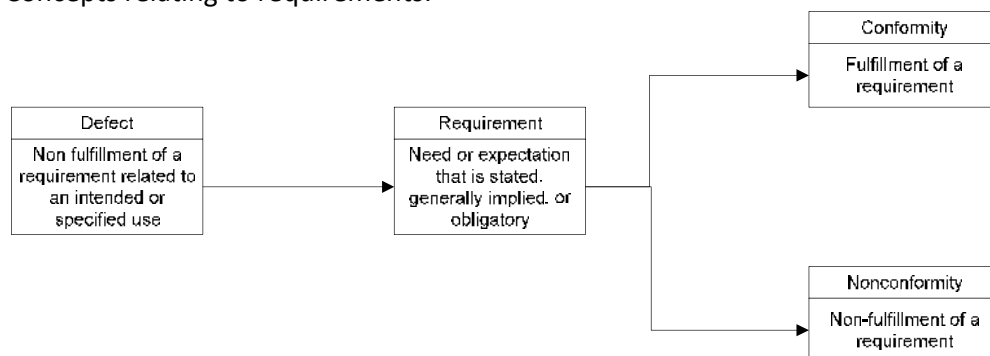
- Confirm staff aware & available
 - Confirm logistic
 - Confirm guides
 - Safety requirements
 - Question
6. Intermediate & final wash up meeting
- With Management representative and other managers
 - To review the audits findings
 - To discuss non conformances
 - To agree corrective actions
7. Closing meeting agenda
- Thank the auditees and reintroduce the team
 - Recap reason, scope & criteria
 - Review audit plan and methods
 - Report the observations, positive & negative
 - Disclaimer
 - Overall summary
 - Questions & answers
 - Corrective actions & Time scale
 - Recommendation
 - Follow up

NCR's (Non Conformity Reports)

What is nonconformance?

In ISO 9000:2005 Nonconformance is “Non fulfillment of a requirement”

Concepts relating to requirements:



Conformance with audit criteria \neq Legal compliance

Non conformity Report:

- Not set rules: however all have these two parts:
 - The requirement (what was supposed to be)
 - The evidence (What actually is)

- Different organizations have different formats
 - Use the format chosen by your client or firm

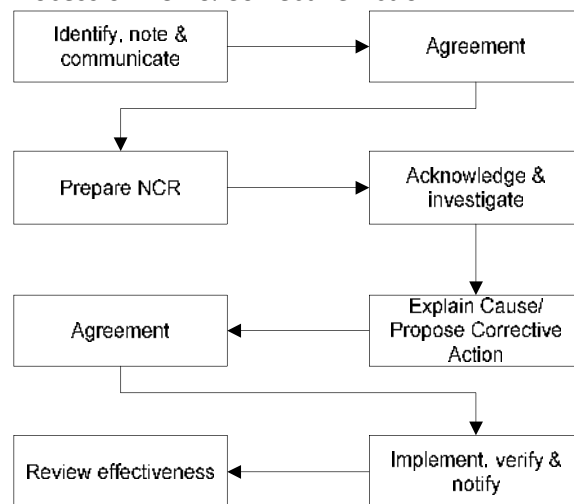
Criteria Non Conformity report:

1. Major
 - A failure of the clients system to address a specified requirement of the standard
 - A frequent or purposeful failure to follow specified requirement written within the company system
 - A failure to achieve the fundamental aim of a system requirement
 - A failure to achieve legal or statutory requirements
 - Multiple minor nonconformities within the same requirement of the standard or company system
 - A purposeful failure of the company to correct nonconformities
2. Minor
 - Minor indicates the issue is not significant
 - The system is not threatened
 - “Noise in the system”
 - Isolated instance where a requirement has not been fulfilled
 - If it is not a MOJOR NC then It is a Minor NC
3. Opportunity For Improvement (OFI)
4. Observer

Corrective action: “action to eliminate the cause of detected nonconformity or other undesirable situation”

Preventive action: “Action to eliminate the cause of a potential nonconformity”

Process of NCR & Corrective Action



5. Kesimpulan

Poin penting yang dapat dijadikan simpulan adalah sebagai berikut;

- Jika suatu lembaga atau organisasi mau menerapkan ISO, yang paling pertama harus dilakukan adalah mengerti, memahami, dan merealisasikan Quality Management System.
- Dalam ISO semua yang tertulis harus dilakukan, dan semua yang dilakukan harus tertulis, serta melakukan continuous improvement.
- Untuk mengimplementasikan ISO suatu lembaga Harus:
 1. Menentukan (establish), mendokumentasikan (documented), mengimplementasikan (implementation), memelihara (maintain), dan melakukan perbaikan berkesinambungan (continuous Improvement) (lihat klausul 4.1, klausul tersebut hukumnya wajib)
 2. Memiliki MR/Management Representative (lihat klausul 5 mengenai Management responsibility). Seorang MR adalah anggota dari Top management yang diangkat dengan SK Pimpinan yang berlaku sesuai dengan kompetensi yang dimilikinya dan diberi otoritas terhadap Penjaminan mutu lembaga
 3. Menentukan semua proses yang ada dalam lembaga, menentukan urutan dan interaksi antar proses, menetapkan metode dan criteria dari proses-proses tersebut, menentukan resources-nya serta supportingnya, melakukan monitoring, pengukuran, dan penganalisisan proses, dan mengimplementasikan continuous improvement.
- Quality manual wajib dimiliki oleh lembaga (lihat klausul 4.2), dimana quality manual itu sendiri berisi tentang:
 1. Scope
 2. Quality Policy
 3. Quality Objective
 4. Exclusions clause including specific causes
 5. Description of process interaction
 6. Matrix relation of process and clause ISO
 7. 6 Procedure should be documented
 - 7.1. Control of document (clause 4.2.3)
 - 7.2. Control of record (clause 4.2.4)
 - 7.3. Internal audit (clause (8.2.2)
 - 7.4. Control of nonconforming product (clause 8.3)
 - 7.5. Corrective action (clause 8.5.2)
 - 7.6. Preventive action (clause 8.5.3)

- Karena mengaudit berarti adalah mencari kesesuaian antara yang dilakukan dengan standar yang berlaku, maka berhubungan dengan klausul 6 mengenai resource management, lebih tepatnya klausul 6.2 (human resources) harus terlebih dahulu dibuat Job description (Tugas Pokok, wewenang, dan tanggung jawab) bahkan bila dibutuhkan Job description ini harus dibuat sampai level staff. Bukan hanya job description tapi juga job specification, dan job analysis nya. Karena kalau job des, job spec, dan job analysis ini tidak ada maka apa yang mau diukur kesesuaiannya, lebih lebih bagaimana cara mengukur kinerjanya.
- Mengingat hierarki dokumen (quality manual, procedure, standardized forms & external documents, records), kemudian juga mengingat setiap apapun yang dilakukan harus tertulis dan yang tertulis harus dilakukan, maka perlu dibuat prosedur yang berlaku dimasing-masing unit/proses. Untuk keperluan pembuatan prosedur ini juga diperlukan Job description yang jelas terkait masing-masing unit dan personilnya.