LECTURE

9

Quality management systems

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LECTURE 9 - OVERVIEW

Quality management system based on ISO 9000

WHAT IS QMS (QUALITY MANAGEMENT SYSTEM)

Goal: Meet customer needs

Quality management system includes organizational structure, procedures, resources, etc.

Today the most widely used QMS is based on ISO 9000 series of standards.

HISTORY OF ISO 9000

Origin: United States Department of Defense MIL-Q-9858 standard in 1959.

Revised into the NATO AQAP (Allied Quality Assurance Publications) series of standards in 1969

Revised into the BS 5179 series of guidance standards published in 1974

Revised into the BS 5750 series of requirements standards in 1979 before being submitted to ISO

ISO 9000:1987 had the same structure as the BS 5750

New versions 1994, 2000, 2008, 2015

ISO 9000

ISO 9000 is now the most popular Quality management system

Standards produced by ISO (International Standardization Organization)

Contains fundamentals of Quality Management System (QMS)

Quite often required in public tenders

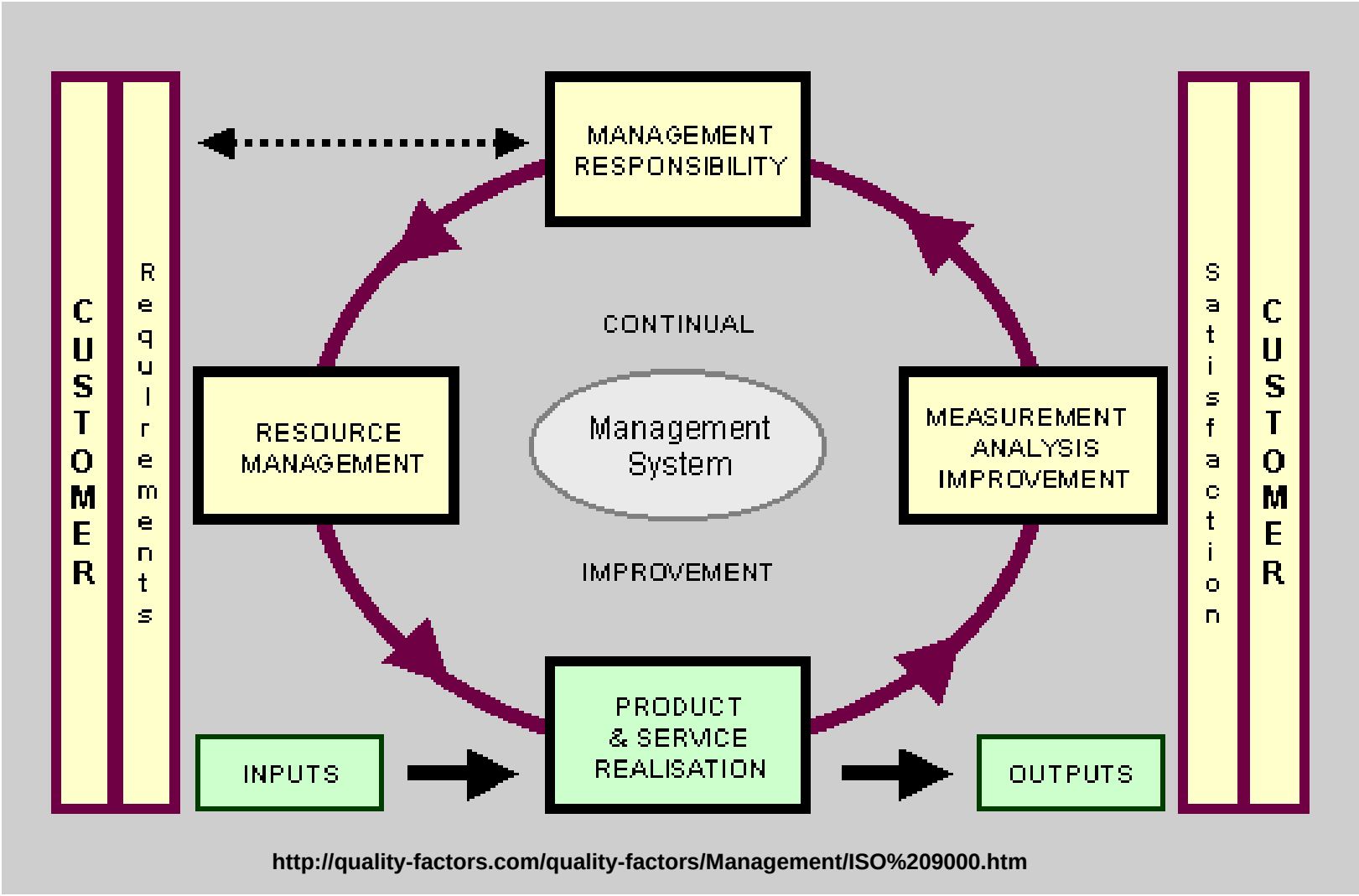
generalized and abstract; must be carefully interpreted to make sense within a particular organization (of any kind – software company, big industry, consulting company, ...)

ISO 9000 DERIVED STANDARDS FOR PARTICULAR FIELDS

- AS9000 – Aerospace Basic Quality System Standard
- PS 9000 for automotive manufacturers
- ISO/TS 16949:2009 for automotive manufacturers
- TL9000 – Telecom Quality Management and Measurement System Standard
- ISO 13485:2012 for mechanical industry
- ISO 13485:2012 for medical industry
- ISO/IEC 90003:2004 for computer software

Etc.

PROCESS BASED QMS



http://quality-factors.com/quality-factors/Management/ISO%209000.htm

ISO 9000

ISO 9000

- Quality management and quality assurance standards guidelines

ISO 9001

- Model for quality assurance in design and development, production, installation and servicing

ISO 9002

- Model for quality assurance in production and installation

ISO 9003

- Model for quality assurance and final inspection and test

ISO 9004

- Quality management and quality system elements, guidelines on how to implement a quality program

ADVANTAGES OF BEING ISO 9001 CERTIFIED

- Optimized company structure and operational integration.
- Improved awareness of company objectives.
- Improved communications and quality of information.
- Responsibilities and authorities clearly defined.
- Improved traceability to 'root causes' of quality problems.
- Improved utilization of time and materials.
- Formalized systems ensure consistent quality and punctual delivery.
- Documented systems provide useful references and training tools.

ADVANTAGES OF BEING ISO 9001 CERTIFIED

- Fewer rejects, therefore, less repeated work and warranty costs.
- Errors rectified at the earliest stage and not repeated.
- Improved relationships with customers and suppliers.
- Improved control during periods of change or growth.
- Use of a recognized logo on stationery and advertisements.
- Improved corporate quality image.
- Ability to bid for 'ISO 9000' contracts at home and abroad.
- Continuous quality assessment by experienced professionals.
- Reduced number of customer audits.
- Improved records in case of litigation.

ISO 9001 CONTENT

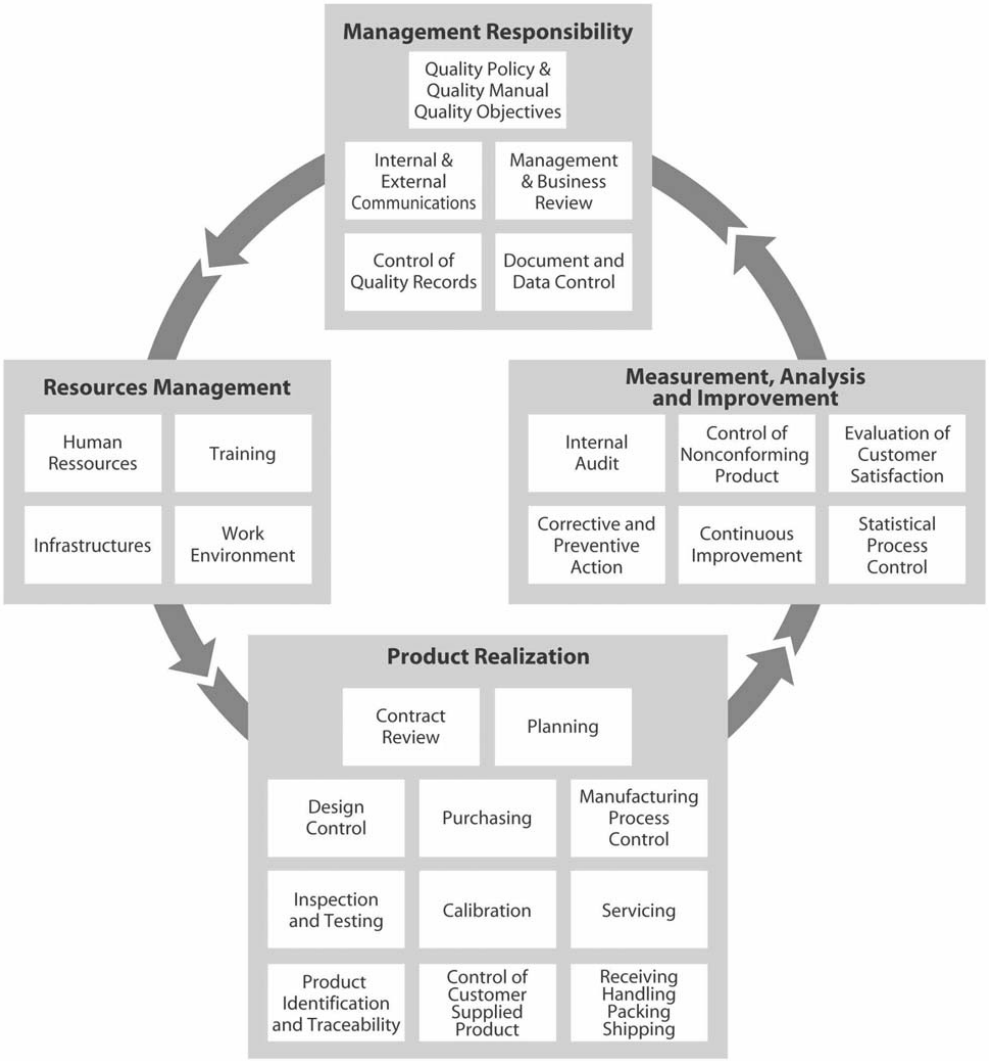
Main parts of the ISO 9001 standard

- Section 4: *Quality Management System*
- Section 5: *Management Responsibility*
- Section 6: *Resource Management*
- Section 7: *Product Realization*
- Section 8: *Measurement, analysis and improvement*

Areas

- Process definition.
- Process control.
- Process measurement.
- Process improvement.
- Administrative support.

QMS PROCESSES



ISO 9001 CONTENT
– Management responsibility

Management responsibility

ISO 9001 must be introduced from the management

Starting from Management Plan (or System Engineering Management Plan) for the quality program

- Quality policy – must be implemented at all levels
- Organization – description of employees roles and responsibilities
- Verification Resources and Personnel – how to verify compliance to requirements, resources for these activities
- Management representative – who is responsible for ISO implementation and maintenance
- Management reviews – when, how

ISO 9001 CONTENT
– Management responsibility

Control of Quality Records.

procedures to collect, maintain, and provide access to quality records. This requirement may be met by a configuration control system database

Quality system

all procedures documented and implemented

- Procedures or methodology manuals – describing system engineering methodologies, methodology for optimization
- Quality planning manuals- how quality requirements will be met

ISO 9001 CONTENT
– Management responsibility

Document and data control

Establishing, documenting and maintaining procedures to control all documents and data

- Ensure up-to-date SDLC (System development life cycle) documents are accessible as needed and where needed.
- Destroy obsolete SDLC documents and replace them by current versions, and notify all personnel of that fact.
- Review and approve SDLC documents, incorporate the reason for changes in the SDLC documents.
- Circulate a master list of SDLC documents, with current revision status.
- Reissue SDLC documents after a number of changes have been made, as appropriate, instead of attaching change pages to the original.

ISO 9001 CONTENT – Resources management

Training.

procedures to:

- Identify training needs.
- Provide appropriate training.
- Identify appropriate qualifications for the personnel who will perform the training.
- Maintain records of which personnel received which training courses, and when the training took place.

ISO 9001 CONTENT – Product realization

Design control

Maintaining procedures to control and verify the design of the product

- Procedures to control and verify designs.
- The orderly transfer between stages in the System Development Life Cycle (SDLC).
- Plans that identify the responsibility for the design and development activity.
- Activities and the resources allocated to them.
- An Interface Control Document (ICD) between the different departments in the company defining their organizational and technical interfaces.
- The methodology for verifying the system requirements.
- The methodology for validating that the system meets he requirements.
- The procedure for identification, and appropriate review and approval of all changes and modifications

ISO 9001 CONTENT – Product realization

Purchasing

documented procedures regarding

- Select sub-contractors on their basis to meet the requirements of the sub-contract, and on their history of past performance.
- Establish and maintain a list of acceptable subcontractors.
- Ensure that every sub-contractor has a quality system.
- Select Commercial-off-the-Shelf (COTS) component suppliers on their basis to meet the need in a timely manner, and on their past performance.
- Ensure that the purchasing documentation is clear, concise, correct, and communicates the need in an effective manner.
- Ensure that the purchasing process contains a feedback mechanism so that purchase orders and subcontracts are reviewed before being placed.
- Verify the deliverables from a sub-contractor at source, namely an on-site acceptance test, prior to shipment.

ISO 9001 CONTENT – Product realization

Control of customer supplied product.

Procedures to verify, store and maintain customer supplied products for incorporation into the product, applicable both for software and hardware

Product identification and traceability

procedures regarding

- Identify and trace requirements from applicable authorized sources.
- Set up and use a configuration control system.
- Retain manufacturing and test records.

These capabilities allow speedy assessment of the:

- Effect of proposed changes to requirements.
- Scope of rework or other damage control techniques in the event of problems occurring down schedule.

ISO 9001 CONTENT – Product realization

Inspection and Testing.

Procedures regarding

- Inspect purchased COTS products prior to integration n the system. This applies to software as well as microcomputers, disk drives and other hardware elements.
- Be able to process a waiver of receipt inspection in the event of urgent need.
- Develop a test plan for the product under development.
- Perform in-process inspection and testing at various checkpoints in the SDLC.
- Perform final acceptance test prior to handover to the customer.
- Determine the disposition in the event of nonconformance to a test.
- Maintain and make use of inspection and test records.

ISO 9001 CONTENT – Product realization

Handling, Storage, Packaging, Preservation and Delivery.

Procedures to

- Handle, store and ship the system to the customer's location.
- Maintain the quality of the product after on-site inspection through the delivery and installation process at the customer's location.
- Restrict access to the product to authorized personnel during the SDLC.

Servicing.
To meet this section of the standard, the procedures to:

- Resolve post-delivery problems including latent defects.
- Maintain records of post-delivery activities.

ISO 9001 CONTENT – Product realization

Process control

procedures in order to deliver the product in a cost-effective manner, under controlled conditions

- Monitoring and controlling to ensure the performance and appropriate tailoring of the SDLC (system development life cycle) methodology.
- Minimizing latent defects in the system. Latent defects in systems engineering tend to show up as bugs in the software, interface problems, and performance gaps after the system has been accepted and placed into operation.

Contract Review

Maintaining processes for contract review and coordination of these activities

- Change control
- Supplier‘s capability to perform – there are sufficient personnel
- Documentation of milestone reviews – description of procedures,

ISO 9001 CONTENT – Product realization

Inspection, Measuring and Test equipment.

procedures dealing with

- Verify all hardware test equipment have the appropriate resolution to make the necessary measurements.
- Calibrate all test equipment used in measuring the performance of the system.
- Periodically check the calibration of the test equipment.
- Test software tools to verify they have the capability to make the measurement.
- Place the software tools used to test the system under configuration control.
- Maintain and make use of inspection and test records.

Inspection and Test Status

Procedures to

- Maintain configuration control over the product in each stage in the SDLC.
- Issue a Discrepancy Report (DR) when a problem is noted at a checkpoint in the SDLC.
- Maintain records to identify the person who approved a product at a checkpoint in the SDLC.

ISO 9001 CONTENT
– Measurement, analysis and improvement

Control of Nonconforming Products.

procedures to

- Separate nonconforming products from conforming products.
- Track DRs (discrepancy reports) and their resolution.

Corrective and Preventative Action.

Procedures to

- Investigate the root cause of a DR and determine the corrective action to be taken to prevent recurrence.
- Detect and eliminate potential causes of nonconformance in the process and product.
- Review the effectiveness of the proposed corrective action.
- Maintain records of DRs and corrective actions.

ISO 9001 CONTENT
– Measurement, analysis and improvement

Internal Quality Audits.

Procedures to

- A methodology for the conduction of internal audits to verify conformance to the ISO 9001 Standard.
- An independent evaluation of the audit results.
- A review of the audit results with the personnel responsible for the activity audited.
- Verification that the recommendations of the audit are carried out. The recommendations of one audit

Statistical Techniques.

Must have and follow procedures to:

- Identify adequate statistical techniques for verifying the acceptability of the process and product.
- Use statistical techniques for verifying

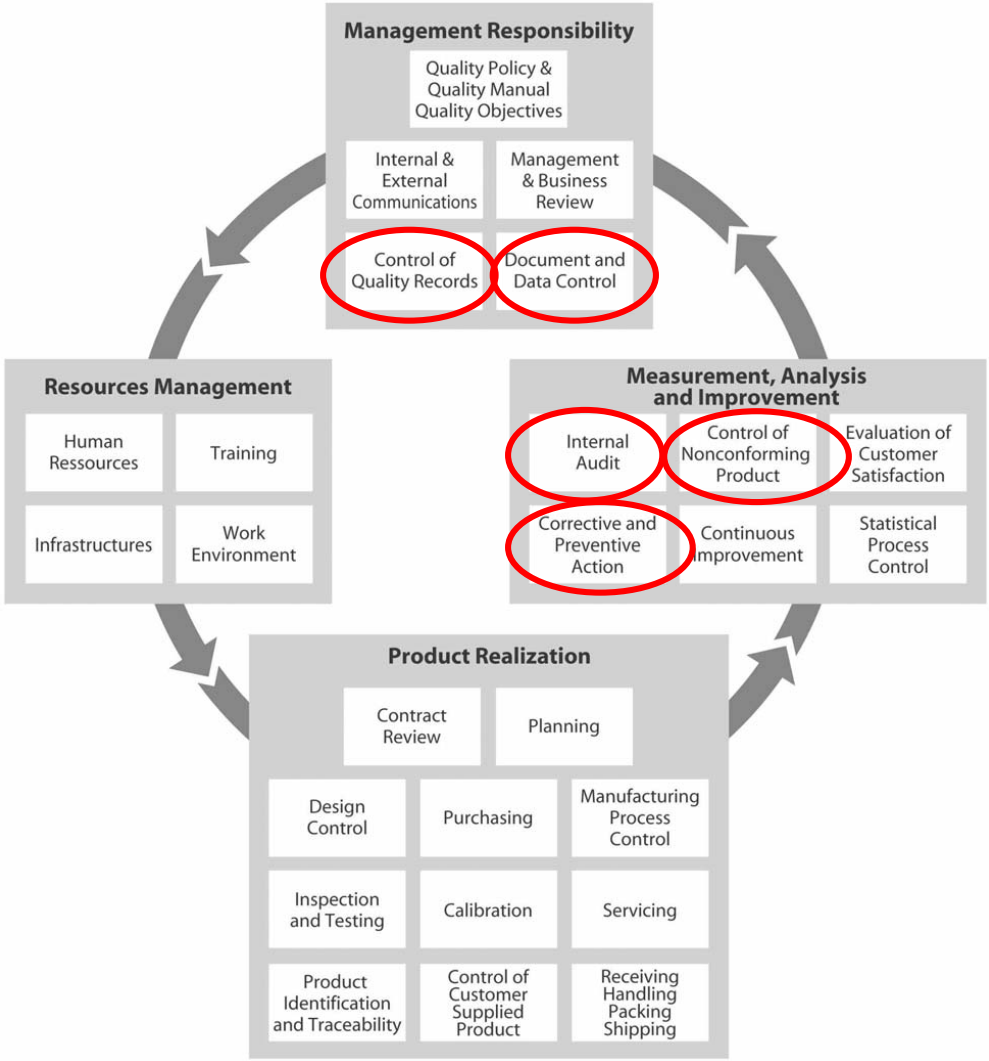
OBLIGATORY PROCEDURES

The standard specifies that the organisation shall issue and maintain the following six documented procedures:

- Control of Documents (4.2.3)
- Control of Records (4.2.4)
- Internal Audits (8.2.2)
- Control of Nonconforming Product / Service (8.3)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)

- + any other procedures required for its effective operation

QMS PROCESSES



QMS DEFINITIONS

Opportunity for Improvement a situation/condition of the QMS that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for an organization to improve its current status.

Minor Non-conformance is a non-conformity that, based on the judgment of the auditor, is not likely to result in the failure of the QMS or reduce its ability to assure a controlled process.

Major Non-conformance the absence, omission or total breakdown of a system to meet a specified requirement.

A number of minor non-conformities against one requirement can represent a total breakdown of the system and thus be considered a major non-conformity.

Preventive action is taken when we anticipate a potential problem and take action to eliminate the possible causes to prevent the occurrence a non-conformance.

Corrective action is taken upon detection of a non-conformance to prevent it from happening again; we act to ‘prevent’ a repeat of a detected non-conformance.

ACHIEVING ISO 9001 CERTIFICATION

Requirements

- Documented processes
- Proof that the processes are performed as documented

To achieve ISO 9001 certification can take up to 2 years

- Changes must be planned
- Company has to function according the processes for several months to be able to prove compliance with the process

ISO 9001 ACCREDITATION

Certified according ISO 9001:2008

Accredited Certification Bodies (CB) Certification bodies operate under standard, ISO/IEC 17021, accreditation bodies operate under ISO/IEC 17011

Audited based on an extensive sample of its sites, functions, products, services and processes

Basic audit principle

- Tell me what you do *(describe the business process)*
- Show me where it says that *(reference the procedure manuals)*
- Prove that this is what happened *(exhibit evidence in documented records)*

ISO 9001 ACCREDITATION

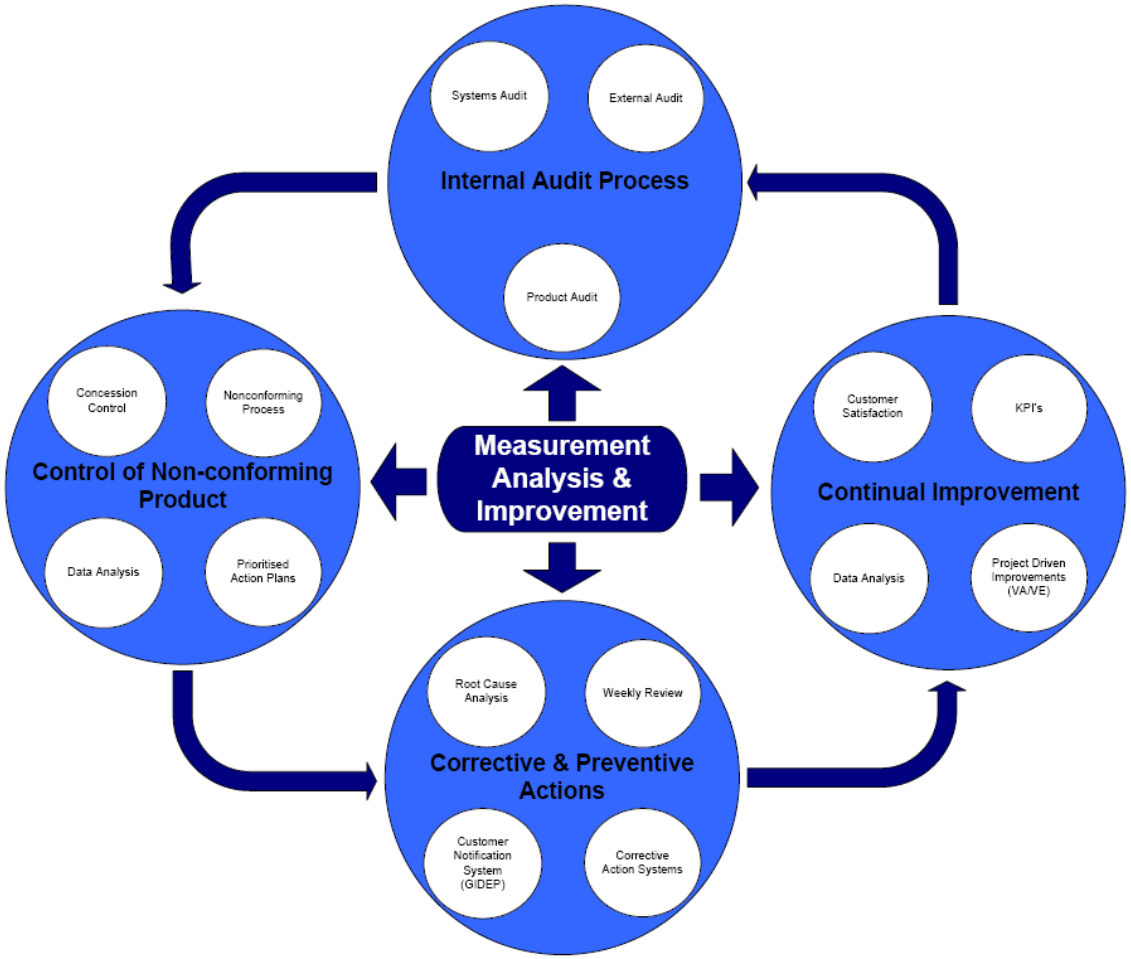
certificate is limited by a certain scope – what the company is doing

must be renewed at regular intervals, at least every three years

Examples of certification authorities:

- EuroCert
- TÜV
- United Registrar of Systems
- TAYLLOR & COX
- Moody International
- Lloyd's Register Quality Assurance
- CQS
- ...

QMS


Systems Audit
External Audit
Internal Audit Process
Product Audit
Concession Control
Nonconforming Process
Control of Non-conforming Product
Data Analysis
Prioritised Action Plans
Measurement Analysis & Improvement
Customer Satisfaction
KPI's
Continual Improvement
Data Analysis
Project Driven Improvements (VA/VE)
Root Cause Analysis
Weekly Review
Corrective & Preventive Actions
Customer Notification System (GIDEP)
Corrective Action Systems

EXAMPLES OF PROCEDURES

Document control procedure

Types of documents – external / internal

Documents, forms, records

Versioning of documents

Master version / controlled copy / uncontrolled copy

Document lifecycle

- Issuing controlled document
- Revising documents,
- Recalling documents
- Document change request

EXAMPLES OF PROCEDURES

Audit procedure I.

- Planning
  - Establish and communicate internal audit schedule
  - Establish and implement internal audit plan
  - Appoint the audit team leader where required
  - Select the audit team
  - Assign audit duties to the auditor
- Preparation
  - Review relevant QMS documents and records
  - Determine their adequacy with respect to the audit criteria
  - Review relevant requirements of ISO 9001:2008
  - Review and prepare the internal audit checklist
  - Arrange audit appointment
- Audit
  - Sample and observe necessary process inputs/outputs
  - Record objective evidence to verify process compliance
  - Generate and record audit findings

EXAMPLES OF PROCEDURES

Audit procedure II.

•Wrap-up meeting

- Decide whether any non-conformance observed should be included in correction reports or whether they can be solved immediately
- Minor areas of non-conformance are taken care of immediately, while a conclusion for the audit as a whole is written down
- An audit report is prepared which is examined together with the manager responsible for the area in question
- Corrective actions are reviewed by the manager responsible and close out action is agreed upon
- The audit leader and responsible manager sign off audit report
- The reports are given to the QMR & the responsible manager

•Follow-up

- Ensure corrective actions are closed-out within the agreed timeframe
- Ensure non-conformances are closed-out within the agreed timeframe
- Ensure status of corrective actions and non-conformances communicated to the QMR
- Provide feedback on the audit process

EXAMPLES OF PROCEDURES

Audit procedure III.

- Reporting
  - Review audit conclusions
  - Indentify trends
  - Make recommendations for improvement
  - Finalise internal audit report
  - Issue internal audit report to Top Management
- Review
  - Consider and act upon audit findings during Management Review
  - Use the internal audit report to promote best practice

EXAMPLES OF PROCEDURES

Management review

- Frequency,
- Required management team,
- Mandatory inputs,
- Outputs and quality records
  - How the results of management review are used
  - What criteria should be met
  - Which corrective actions will be taken

QMS FORMS - EXAMPLES

Master document index

Document issue sheet

Document change request

Master quality record index

Internal audit schedule,

Internal audit plan,

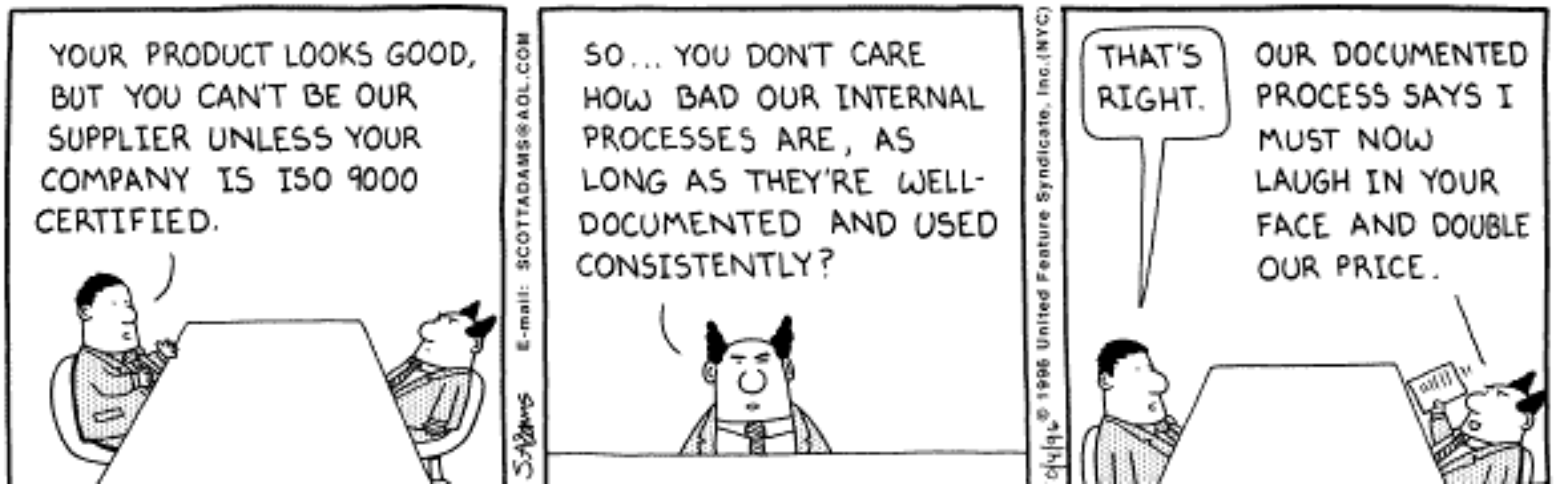
Internal audit assignment,

Internal audit gap analysis,

Internal audit report,

Internal audit feedback

ISO 9001 – subject of jokes


YOUR PRODUCT LOOKS GOOD, BUT YOU CAN'T BE OUR SUPPLIER UNLESS YOUR COMPANY IS ISO 9000 CERTIFIED.
SO... YOU DON'T CARE HOW BAD OUR INTERNAL PROCESSES ARE, AS LONG AS THEY'RE WELL-DOCUMENTED AND USED CONSISTENTLY?
THAT'S RIGHT.
OUR DOCUMENTED PROCESS SAYS I MUST NOW LAUGH IN YOUR FACE AND DOUBLE OUR PRICE.
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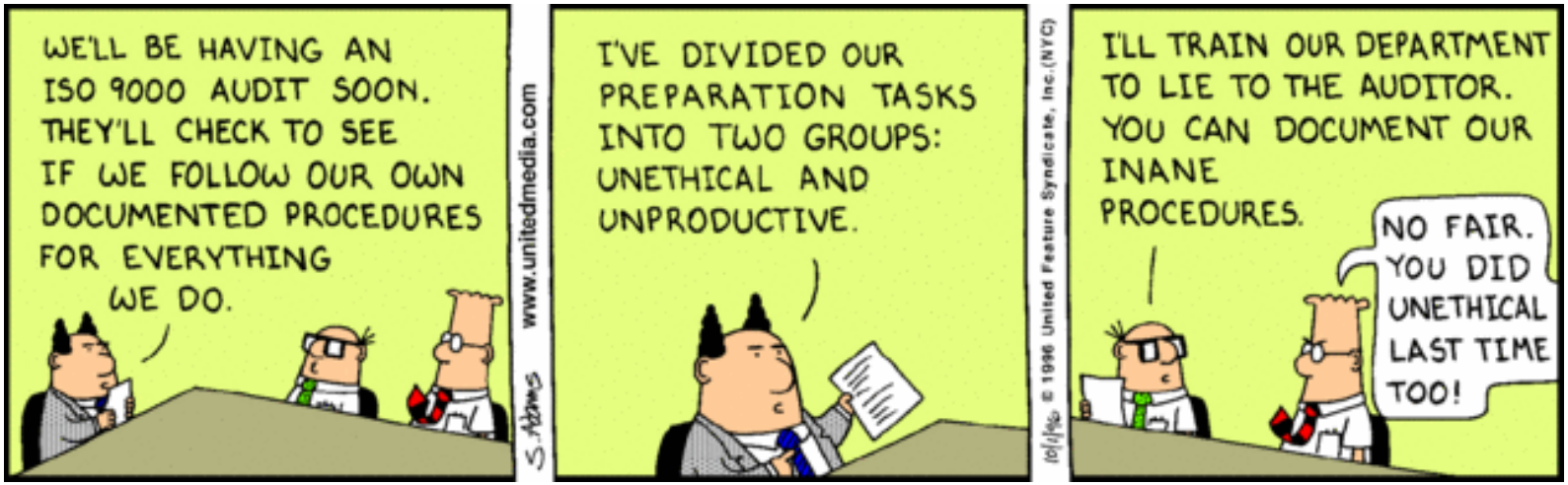
WE'LL BE HAVING AN ISO 9000 AUDIT SOON. THEY'LL CHECK TO SEE IF WE FOLLOW OUR OWN DOCUMENTED PROCEDURES FOR EVERYTHING WE DO.
I'VE DIVIDED OUR PREPARATION TASKS INTO TWO GROUPS: UNETHICAL AND UNPRODUCTIVE.
I'LL TRAIN OUR DEPARTMENT TO LIE TO THE AUDITOR. YOU CAN DOCUMENT OUR INANE PROCEDURES.
NO FAIR. YOU DID UNETHICAL LAST TIME TOO!
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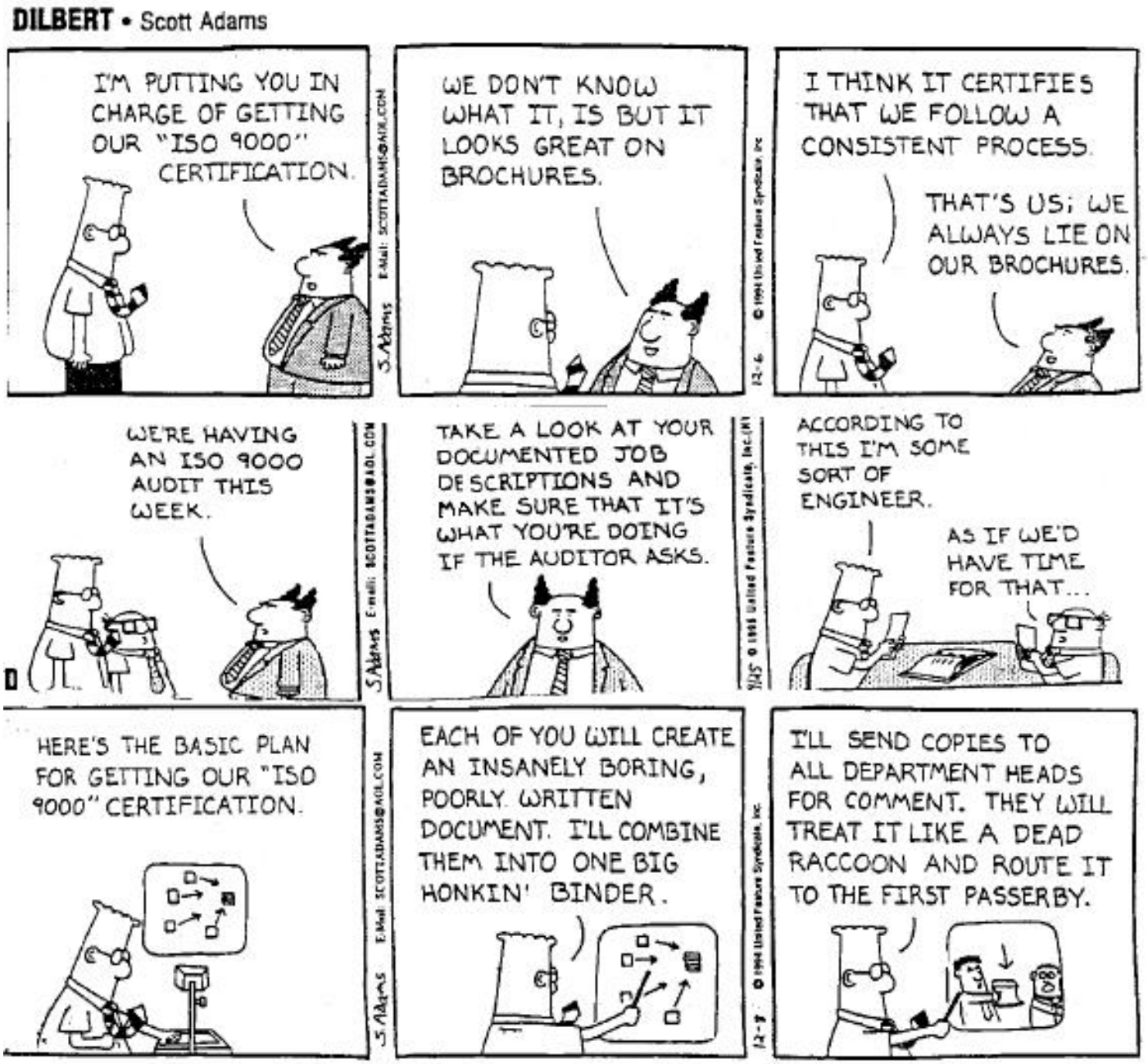
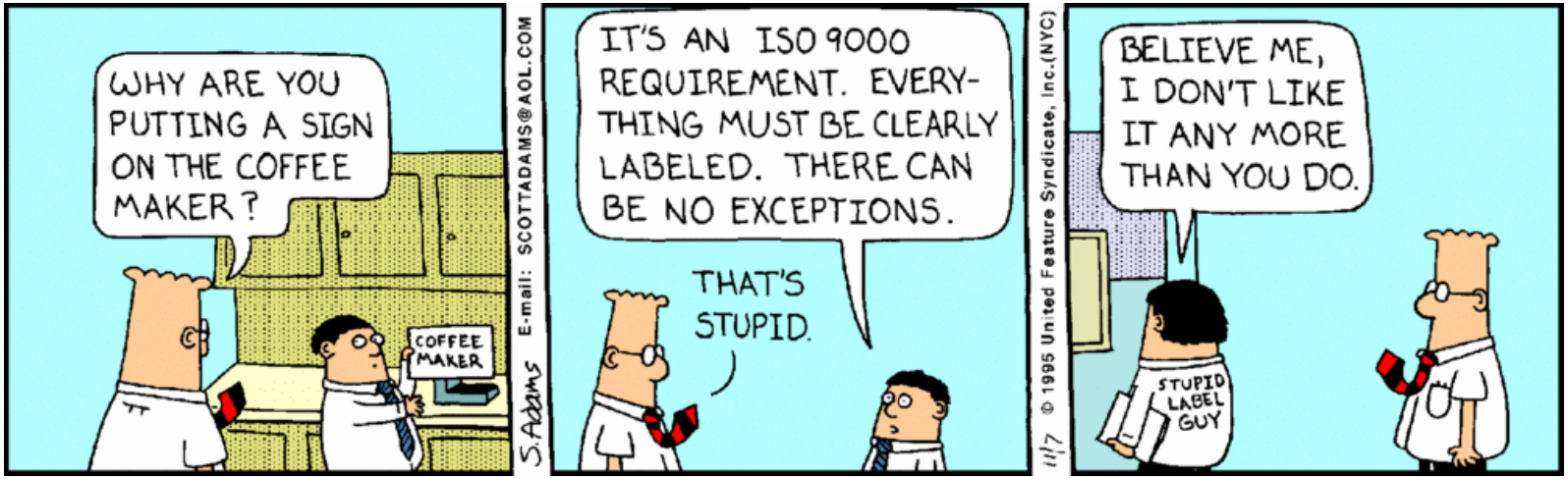

DILBERT • Scott Adams
I'M PUTTING YOU IN CHARGE OF GETTING OUR "ISO 9000" CERTIFICATION.
WE DON'T KNOW WHAT IT, IS BUT IT LOOKS GREAT ON BROCHURES.
I THINK IT CERTIFIES THAT WE FOLLOW A CONSISTENT PROCESS.
THAT'S US; WE ALWAYS LIE ON OUR BROCHURES.
WE'RE HAVING AN ISO 9000 AUDIT THIS WEEK.
TAKE A LOOK AT YOUR DOCUMENTED JOB DESCRIPTIONS AND MAKE SURE THAT IT'S WHAT YOU'RE DOING IF THE AUDITOR ASKS.
ACCORDING TO THIS I'M SOME SORT OF ENGINEER.
AS IF WE'D HAVE TIME FOR THAT...
HERE'S THE BASIC PLAN FOR GETTING OUR "ISO 9000" CERTIFICATION.
EACH OF YOU WILL CREATE AN INSANELY BORING, POORLY WRITTEN DOCUMENT. I'LL COMBINE THEM INTO ONE BIG HONKIN' BINDER.
I'LL SEND COPIES TO ALL DEPARTMENT HEADS FOR COMMENT. THEY WILL TREAT IT LIKE A DEAD RACCOON AND ROUTE IT TO THE FIRST PASSERBY.



Thank you for your attention

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