Internal Auditor Training

12th, 13th November 2007

Presented to

AUROVISION Pvt Ltd

by

ePrama Technologies Pvt Ltd

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General Information

- Scope of this training is to build a team of Internal Auditors for Aurovision
- The training material has been developed by ePrama and shall not be used or shared by Aurovision, with any one outside Aurovision, with out the written consent from ePrama.
- Training duration is 2 full days.
- Soft copy of the training material will be delivered to the MR, who in turn may share the same within Aurovision
- The participants are encouraged to get their queries related to the training topic clarified during the course of the session.
- Cooperation from the participants is solicited to ensure that the training is completed as per the schedule and is effective.
- All participants are required to sign attendance register daily, and provide their feedback at the end of the training.
- All participants are requested to keep their cell phones switched off during the training sessions.

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General Information

- Start time: 9:00 AM
- End time: 5:00 PM
- Breaks:
  - Tea/coffee: 2 breaks of 15 min each
  - Lunch: 12:30 to 1:00 PM
- Time management: Sandeep H, ePrama
- Training coordinator: Rahul Date, Aurovision

Let us respect the time of each other and be in our seat 5 min before the start of a session

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DAY – 1

- Introduction to ISO 9000
- The ISO 9001:2000 Overview
- The Requirements of ISO 9001

INTRODUCTION TO ISO 9000

- What is ISO 9001?
- The "Process Approach"?

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What is ISO 9001:2000?

- ISO 9001:2000 is an international standard containing requirements for establishing and maintaining a company's quality management system.

- A Quality Management System (QMS) is set up by a company to:
  - establish a quality policy and quality objectives, and
  - establish the means to achieve those objectives.

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What is ISO 9001:2000?

- The ISO 9001:2000 QMS standard can be applied to almost any company.
  - Generic model
  - Product manufacturers to Service Providers
  - Not specific to any product or service
  - Does not focus on “What” you produce; but on “How” you produce.
- ISO 9001:2000 requires systems for controlling the processes you use to develop and produce your products and/or deliver your services.
- The world has adopted ISO 9001:2000 as an accepted standard for QMS requirement

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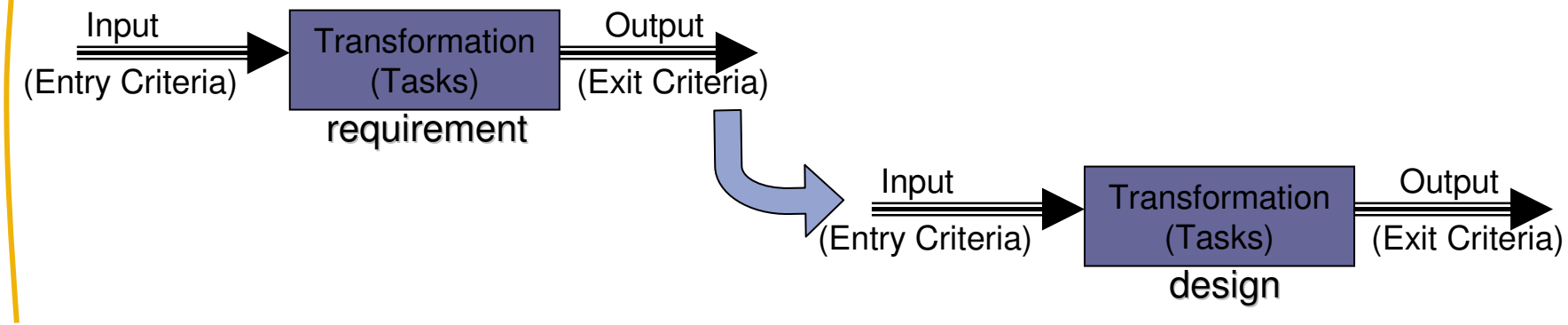
The Process Approach

What is a Process?

- A process is a "set of interrelated or interacting activities which transforms inputs into outputs"

- The output of one process often becomes the input to another "downstream" process.



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The Process Approach

- *What is a Process Approach?*
  - *Identifying and defining the processes (that are essential to the business)*
  - *Implementing and institutionalizing the processes (training, practice, monitor, mentor) across the organization*
  - *Managing the processes (and the interactions and handoffs between these processes), and*
  - *(Learning from the experience and) Improving the processes continually.*

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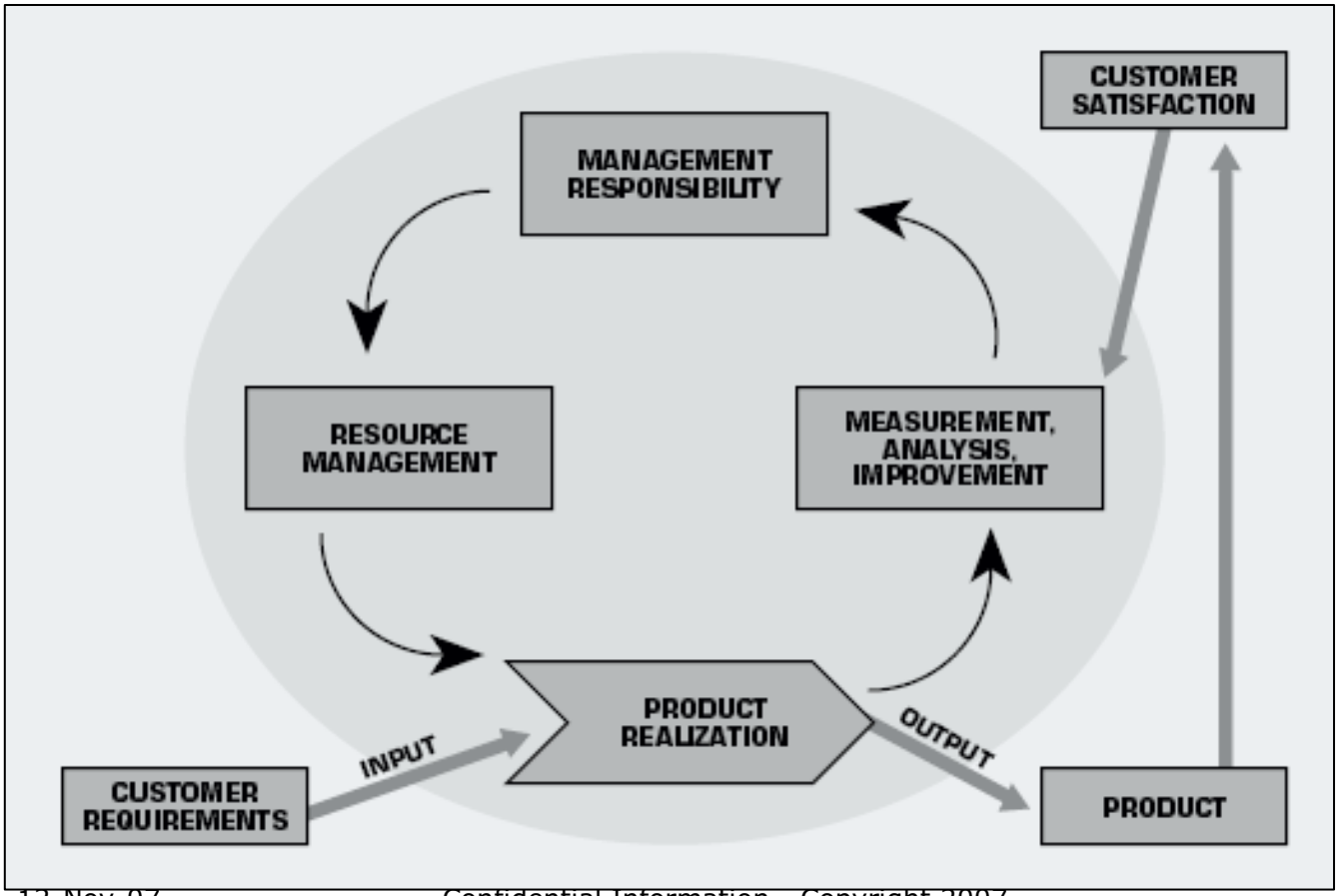
The Process Approach

The goal is to focus on the needs of the customer and continually improve the processes



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The ISO 9001:2000 Approach

- A brief history of ISO 9000
- Major Elements of QMS
- Quality Management Principles
- Meaning of Registration
- Registration Process
- Sample certificate
- Why Aurovision wants to be ISO 9001:2000 Certified?

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A brief history of ISO 9000

- **Pre ISO 9000**
  - World War II: many British high-tech manufacturing industries were facing quality problems.
- **BS 5750**
  - BS 5750 Standard was introduced to document the manufacturing procedures and to prove by record-keeping that the procedures are used
  - Other references: CSA Z299 (Canadian Std); NATO AQAP series and US MIL-SPEC
- **ISO/TC 176**, Quality management & quality assurance approved in 1979.
- **ISO 9000:1987**
  - 1987, International Organisation for Standardization (ISO) adopted BS 5750 as an international standard for Quality Management System.
  - Focus was on conformance with procedures rather than the overall process of management
  - Three models: ISO 9001, ISO 9002, ISO 9003

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A brief history of ISO 9000

- **ISO 9000:1994**
  - Emphasized quality assurance via preventative actions
  - Companies tended to implement its requirements by creating shelf-loads of procedure manuals
  - Three models: ISO 9001, ISO 9002, ISO 9003

- **ISO 9001:2000**
  - Combines the three standards 9001, 9002, and 9003 into one, called 9001
  - Demands involvement by upper executives, in order to integrate quality into the business
  - Improve effectiveness via process performance metrics — numerical measurement of the effectiveness of tasks and activities
  - Continual process improvement and tracking customer satisfaction were made explicit

- **Future Version : 2008**
  - TC 176, the ISO 9001 technical committee, has started its review on the next version of ISO 9001, which will be termed the ISO 9001:2008 standard

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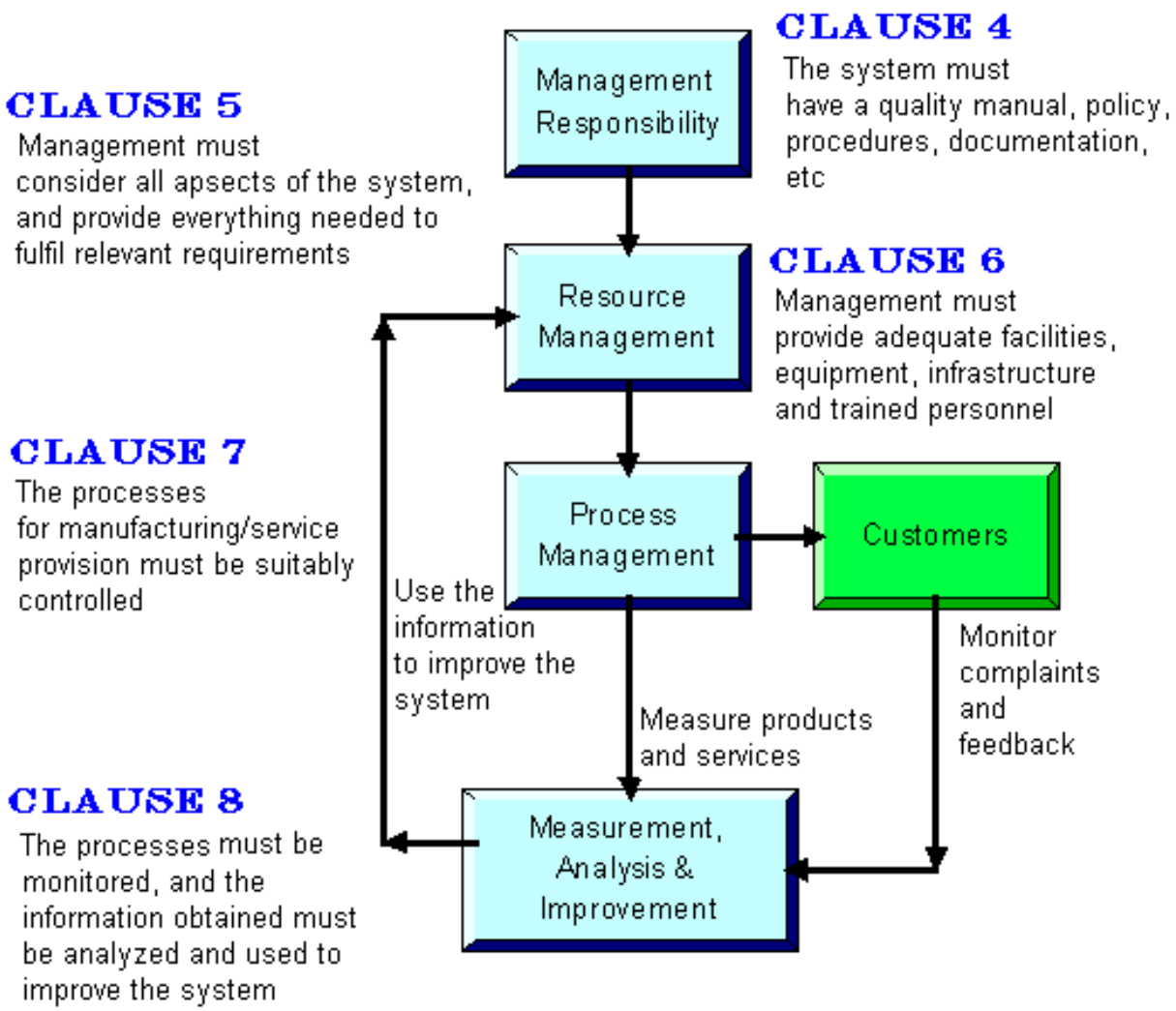
Major Elements of QMS



Major Elements of QMS

- ISO 9001 Framework is divided into Four Major Elements based on Process Approach:
  - Management Responsibility processes:
    - includes planning and management review. (Clause 5).
  - Resource management processes:
    - includes human resources, infrastructure, and the work environment. (Clause 6).
  - Product realization processes:
    - includes sales order review, product design, purchasing, calibration, and the actual "production" of your product or service. (Clause 7).
  - Measurement, analysis and improvement processes:
    - includes internal auditing, inspection, testing, and corrective/preventive action. (Clause 8).

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Major Elements of QMS

Management Responsibility:

1. Management commitment
2. Customer focus
3. Quality policy
4. Planning
5. Responsibility, authority and communication
6. Management review

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Major Elements of QMS

Resource Management:

1. Provision of resources
    1. Human resources
    2. Infrastructure
    3. Work environment

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Major Elements of QMS

Product Realization:

1. Planning of product realization
2. Customer-related processes
3. Design and development
4. Purchasing
5. Product and service provision
6. Control of monitoring and measuring devices

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Major Elements of QMS

Measurement, Analysis & Improvement:

1. Monitoring and measurement
2. Control of nonconforming product
3. Analysis of data
4. Improvement

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Quality Management Principles

- Eight Quality Management Principles:
  1. Customer-focused organization
  2. Leadership
  3. Involvement of people
  4. Process approach
  5. System approach to management
  6. Continual improvement
  7. Factual approach to decision-making
  8. Mutually beneficial supplier relationships

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Quality Management Principles

1. Customer-focused organization

- Principle:
  - Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

- Action expected:
  - Understand current and future customer needs and expectations. Measure customer satisfaction and act on it.

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Quality Management Principles

2. Leadership

- Principle:
  - Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

- Action expected:
  - Establish vision, direction and shared values. Set challenging targets and goals and implement strategies to achieve them. Coach, facilitate and empower people.

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Quality Management Principles

3. Involvement of people

- Principle:
  - People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

- Action expected:
  - Create personal ownership of an organization's targets and goals, by using its peoples` knowledge and experience, and through training achieve involvement in operational decisions and process improvement.

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Quality Management Principles

4. Process approach

- Principle:
  - A desired result is achieved more efficiently when related resources and activities are managed as a process.

- Action expected:
  - Explicitly identify internal/external customers and suppliers of processes. Focus on the use of resources in process activities, leading to effective use of people, equipment, methods and materials.

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Quality Management Principles

5. System approach to management

- Principle:
  - Identifying, understanding and managing a system of interrelated processes for a given objective improve the organization's effectiveness and efficiency*.

- Action expected:
  - Identify a set of processes in a system. Understand their interdependencies. Align the processes with the organization's goals and targets. Measure results against key objectives.

* "Effective" means that the QMS works and achieves its objectives.
"Efficient" means that the QMS uses minimum resources

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Quality Management Principles

6. Continual Improvement

- Principle:
  - Continual improvement should be a permanent objective of the organization.

- Action expected:
  - Set realistic and challenging improvement goals, provide resources and give people the tools, opportunities and encouragement to contribute to the continual improvement of the processes.

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Quality Management Principles

7. Factual approach to decision-making

- Principle:
  - Effective decisions are based on the analysis of data and information.

- Action expected:
  - Decisions and actions are based on the analysis of data and information to maximize productivity and to minimize waste and rework.
  - Effort is placed on minimizing cost, improving performance and market share through the use of suitable management tools and technology.

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Quality Management Principles

8. Mutually Beneficial Supplier Relationship

- Principle:
  - An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

- Action expected:
  - Establish strategic alliances or partnerships, ensuring early involvement and participation defining requirements for joint development and improvement of products, processes and systems. Develop mutual trust, respect and commitment to customer satisfaction and continual improvement.

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Meaning of Registration

- A registrar is a company that will audit your company's quality management system to see if it is meeting all the necessary requirements
  - TUV, BVQI, AQA ….
- Aurovision will be "registered" (or "receive ISO 9001:2000 Certification") by a registrar on successful completion of Certification Audit
- If certain aspects of ISO 9001 (clause) do not apply to a company (for example, if your company doesn't develop its own product designs), that clause may be excluded from the scope of its registration.
  - The clause no: 7.6 Control of monitoring and measuring devices is not applicable in a typical software development company.

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Meaning of Registration

- Once the QMS is in place and been implemented and is validated by internal audits, a Registrar selected by Aurovision (TUV/AQA/BVQI) will come and audit.
  - If all the criteria are being followed, the company will be ISO 9001 Registered and Certification will be issued.
  - Registered companies can put their Registration mark in marketing materials, website etc.
  - Potential customers will know that you have a good Quality Management System in Place

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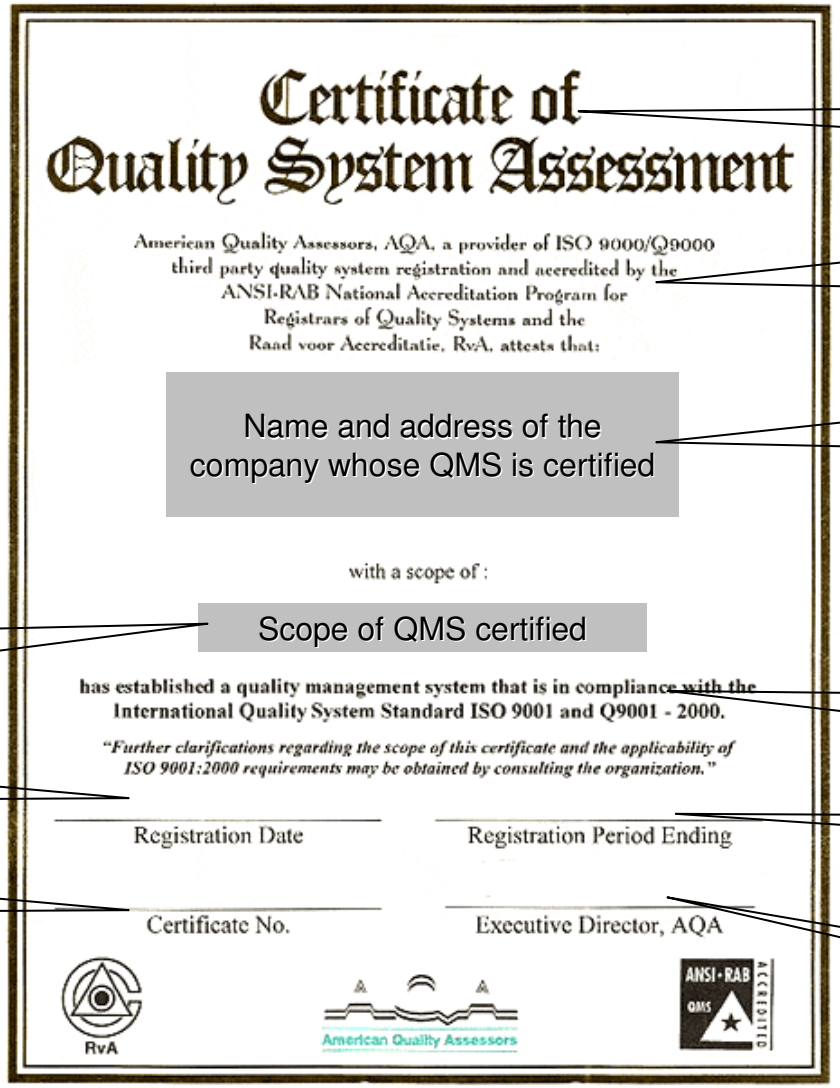
Registration Process

Sample Certificate



Certificate of
Quality System Assessment

American Quality Assessors, AQA, a provider of ISO 9000/Q9000 third party quality system registration and accredited by the ANSI-RAB National Accreditation Program for Registrars of Quality Systems and the Raad voor Accreditatie, RvA, attests that:

Name and address of the company whose QMS is certified

with a scope of :

Scope of QMS certified

has established a quality management system that is in compliance with the International Quality System Standard ISO 9001 and Q9001 - 2000.

"Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organization."

Registration Date

Registration Period Ending

Certificate No.

Executive Director, AQA

RvA

American Quality Assessors

ANSI-RAB QMS ACCREDITED

Name of the certificate

Name of the certifying org (AQA, TUV etc)

Name of the Company Certified

Scope of the Certification

Ref to standard For compliance

Date of Certification

Validity period

Certificate No

Signature

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Why Certify Aurovision QMS?

- Aurovision Management wants the QMS to be certified against a world class std, as a part of the Quality Journey
- Customers expect and demand their vendors should have a proven processes & practice, certified by a third party,
- Demonstrate our ability to provide quality products and/or services on time and within budget with least defects,
- Competitive advantages in marketing; an improved "quality" image,
- Improved performance due to internal process discipline (less defects / rework),
- A stronger focus on customer satisfaction and continual improvement,
- Better documentation of essentials and audit trail,
- ISO 9001:2000 has become the *de facto* standard.

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The Requirements of ISO 9001

- A reference to clauses of ISO 9001:2000
- ISO 9001:2000 QMS Requirements
- QMS Documentation Hierarchy

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A reference to ISO 9001:2000 Clauses

- 1 Scope
  - 1.1 General
  - 1.2 Application
- 2 Normative References
- 3 Terms and Definitions
- 4 Quality management system
  - 4.1 General requirements
  - 4.2 Documentation requirements
- 5 Management responsibility
  - 5.1 Management commitment
  - 5.2 Customer focus
  - 5.3 Quality policy
  - 5.4 Planning
  - 5.5 Responsibility, authority & communication
  - 5.6 Management review
- 6 Resource management
  - 6.1 Provision of resources
  - 6.2 Human resources
  - 6.3 Infrastructure
  - 6.4 Work environment
- 7 Product realization
  - 7.1 Planning of product realization
  - 7.2 Customer-related processes
  - 7.3 Design and development
  - 7.4 Purchasing
  - 7.5 Production and service provision
  - 7.6 Control of monitoring and measuring devices
- 8 Measurement, analysis and improvement
  - 8.1 General
  - 8.2 Monitoring and measurement
  - 8.3 Control of nonconforming product
  - 8.4 Analysis of data
  - 8.5 Improvement

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ISO 9001:2000 QMS Requirements

1. Scope

1.1 General

- Specifies requirements for a QMS where an organization
  a) Demonstrates its ability to consistently provide product that meets customer and applicable regulatory requirements, and
  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 regulatory requirements.

NOTE: *In this International Standard, the term "product" applies only to the product intended for, or required by, a customer. Product includes Services.*

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ISO 9001:2000 QMS Requirements

1.2 Application

- All requirements are generic;
- Applicable to all organizations, regardless of type, size and product provided.
- This clause allows organizations to claim that relevant sub-clauses do not apply. However, these exclusions can only be claimed against clause 7.
  - So this means that organizations cannot claim (for example) that clause 4.2.4 does not apply to their activities.
  - If a sub-clause is claimed for exclusion, the organization must give a valid reason for the claim.

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ISO 9001:2000 QMS Requirements

2. Normative reference

- Parties to agreements based on this International Standard are encouraged to apply the most recent edition of the normative document.

Note: Parties should procure an authentic original copy of the ISO 9001:2000 standard and manage the same as a controlled copy

- ISO 9000:2005 defines the vocabulary and describes the fundamental principles of quality management systems

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ISO 9001:2000 QMS Requirements

- Some of the terms to remember are:
  - **the product** - the thing that your company provides to the customer
  - **the organization** - your company
  - **the customer** - the people you supply product to
  - **the supplier** - the people who supply you something that contributes to your product
  - **top management** - the company directors, executive management
  - **shall - means "you must"** - you will be audited to ensure you comply with the "shalls"
  - **effectiveness** - means that the QMS works and achieves its objectives.
  - **efficient** - means that the QMS uses minimum resources
  - **quality** - there are many incomprehensible, official definitions. Think of quality as "we keep our promises"

**For detailed definitions, refer to Glossary of Terms: "Glossary of terms"*

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ISO 9001:2000 QMS Requirements

3. Terms and definitions

- This is for information purposes, and states that the use of three terms has been changed from earlier versions of the standard (supplier, organization & customer).

- In ISO 9001:2000, the term “product” can also mean “service”.

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ISO 9001:2000 QMS Requirements

4 Quality management system

4.1 General requirements

- Have a QMS which is kept up to date and continually improving.
- This clause requires that you :
  - identify the processes involved,
  - determine the sequence of operations,
  - determine ways by which you can be sure that the processes are working correctly,
  - ensure that you have sufficient resources for the processes and their monitoring
  - can show that you monitor and improve your system

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ISO 9001:2000 QMS Requirements

4.2 Documentation requirements

4.2.1 General

- Defines that the types of documentation that you must include in QMS:
  - Statements of quality policy and quality objectives
  - A Quality Manual
  - Documented procedures, where required by the standard
  - The records required by the standard as evidence, plus any others that you need, to operate your business

Note: The extent of documentation will depend upon your processes and competence of personnel

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ISO 9001:2000 QMS Requirements

4.2.2 Quality Manual

- Must have an up to date Quality Manual
  - include any exclusions of sub-clause in clause 7 of ISO 9001 for your organization
  - include reference to the procedures that are required by ISO 9000 and defined in the Aurovision QMS
    - keep the procedures separate from the QM, and have separate collections of SOPs, Work Instructions, etc.
- Define the interaction between the various processes. (flow charts, in words, charts etc.)

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ISO 9001:2000 QMS Requirements

4.2.3 Control of Documents

- Ensure that only the correct version of documents is available for use
- Must be reviewed and approved prior to use
- Must be baselined and configuration controlled
- Periodically review them for ongoing suitability (any changes required, still legible, relevant, accessible etc).

Procedure for Control of Documents and Records is required

- Documentation standards for Procedures, Templates, Formats, Guidelines, Checklists, etc.,

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ISO 9001:2000 QMS Requirements

4.2.4 Control of Records

- Keep adequate records as evidence of QMS implementation
- keep them for a defined minimum period (life)
- Have proper and organized repository for the document in a way that they are easily accessible to relevant persons.

Procedure for Control of Documents and Records is must

- what records are required,
- how & where they are stored,
- ensure that they can be retrieved,
- describe their retention time and subsequent disposal

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ISO 9001:2000 QMS Requirements

5 Management Responsibility

5.1 Management Commitment

- Define the commitment of senior management to the development and improvement of the system..
  - Declare the quality policy
  - Identify the Quality Objectives & Measures
  - Conduct management reviews (convened by MR)
  - Ensure that you make sufficient resources available

5.2 Customer Focus

- Define the commitment of Sr. Mgmt towards Customer satisfaction in determining, meeting and enhancing.

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ISO 9001:2000 QMS Requirements

5.3 Quality Policy

- Quality Policy is the most important facet of QMS.
- It is the declaration of the Sr. Mgmt document.
- Is the Top level Document in the QMS.
- Defines your approach to quality in an achievable and demonstrable way.
- Establish a system for reviewing quality objectives
- Review the quality policy during Mgmt Review Meetings

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ISO 9001:2000 QMS Requirements

Do you know Aurovision's Quality Policy?

Quality Policy of Aurovision

Using best industry practices and continuous Process improvement we strive to consistently deliver defect free quality product and services to clients on time within agreed budget

Date:	Approved by:	Director

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ISO 9001:2000 QMS Requirements

5.4 Planning

5.4.1 Quality Objectives

- Have adequate resources to achieve the required level of quality
- define objectives for quality, using measurable terms

5.4.2 Quality Management System Planning

- Provide adequate resources to ensure that quality objectives are planned and identified
- Ensure that the integrity of the system is maintained by following Change Management and Configuration Management

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ISO 9001:2000 QMS Requirements

5.5 Responsibility, Authority & Communication

5.5.1 Responsibility & authority

- Administer the QMS by proper control of documents, structure of the quality system, identifying authority & responsibility, etc
- Identify the responsibilities of the key functions within the organization

5.5.2 Management Representative

- MR is the "Quality Champion”,
- appointed by the "Top Management"
- member of the "management" of your organization
- Responsibilities of MR include:
  - Ensure that the QMS processes are operating correctly,
  - Report performance of the system to the top management
  - promote awareness of customer requirements.

5.5.3 Internal Communication

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ISO 9001:2000 QMS Requirements

5.6 Management Review

5.6.1 General

- Review the operation of the QMS, to ensure it is up to date and effective
- Identify scope for improving the QMS, if any.

5.6.2 Review Input

- Input to the Management Review include:
  - Results of previous audits
  - Customer feedback / complaints
  - Process & product (or service) conformity
  - Status of preventive/corrective actions
  - Follow-up actions from previous reviews
  - Changes that could affect the system
  - Recommendations for improvement

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ISO 9001:2000 QMS Requirements

5.6.3 Review Output

- Improvements to the effectiveness of the QMS
  - Based on the issues, NCs, feedback from practitioners of the QMS
- Improvements to the product/services
  - Based on the Customer feedback, Complaints, identify improvements needed in delivery capabilities, skill building etc.,
- Resources needs to achieve these improvements
  - Resources include human resources as well as IT infrastructure, work environment etc.
- Directions on future Quality Initiatives
  - Future Quality initiative include plan for CMMI, ISO 27001 etc.,

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ISO 9001:2000 QMS Requirements

6. Resource Management

6.1 Provision of Resources

- Provide adequate resources
  - to enhance Customer satisfaction
  - to implement the required processes and
  - to improve them

6.2 Human Resources

6.2.1 General

- Ensure adequately trained people for performing the job effectively and efficiently

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ISO 9001:2000 QMS Requirements

6.2.2 Competence, Awareness & Training

- Identify skills required for the tasks which affect product quality,
- Provide training, etc
- Evaluate the effectiveness of the training,
- Ensure employees are made aware of the importance of their tasks,
- Keep records of the training and experience, etc.

6.3 Infrastructure

- Provide adequate facilities: suitable buildings, workspace, tools & equipment, supporting services.

6.4 Work Environment

- Manage the "human & physical" factors which affect the suitability of your product/services

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ISO 9001:2000 QMS Requirements

7. Product Realization

7.1 Planning of Product Realization

- Define the quality objectives and requirements for the products,
- Ensure adequate plan for all of the processes and sub-processes needed to provide the products/services,
- Plan the required testing activities,
- Identify the records that will be kept, to prove that the product has been properly produced

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ISO 9001:2000 QMS Requirements

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

- Define what your Customer requires from you, (such as legal requirements, warranties, and support, etc)

7.2.2 Review of Requirements Related to the Product

- Ensure that customer requirements are defined properly
  - What it is that you thought the Customer wanted
  - Ensure you have the resources to supply what has been ordered before you accept the order
  - Define how changes in requirements are to be processed

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ISO 9001:2000 QMS Requirements

7.2.3 Customer Communication

- Set up proper communication channels for the Customer to contact your organization, especially for product information, feedback including complaints, enquiries and orders, including amendments

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ISO 9001:2000 QMS Requirements

7.3 Design and Development

7.3.1 Design Planning

- identify the various design / development processes and the related review stages
- identify all relevant responsibilities

7.3.2 Design Inputs

- identify what information is required to design or develop the product or service
  - Include functional requirements, standards, legal requirements
  - similar previous designs and learn from them

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ISO 9001:2000 QMS Requirements

7.3.3 Design Outputs

- Identify the Design outputs (Architecture, HLD, LLD etc)
- Update the Traceability of requirement to Design

7.3.4 Design Reviews

- Review the progress of the design activities at appropriate stages
- Identify and record any problems and propose follow-up actions

7.3.5 Design Verification

- Verify designs; ensure the design meets the design input requirements
- Plans should include the verification activities

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ISO 9001:2000 QMS Requirements

7.3.6 Design Validation

- Ensure that the product or service works correctly in practice
- Validation may include reviews of Customer feedback after release of the product.
- Plans should include the Design Validation activities

7.3.7 Design Changes

- Follow the Change Management process
- All changes should be reviewed and recorded.
- Effect that the changes may have on any sections of the design work already completed or under way (Impact analysis)

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ISO 9001:2000 QMS Requirements

7.4 Purchasing

7.4.1 Purchasing Control

- Selection of the right suppliers
- Clarity of requirement

7.4.2 Purchasing Information

- PO to be clear on the requirements
- Reviewed for adequacy before the PO is sent to the Vendor

7.4.3 Verification of Purchased Product

- Verify that the Vendor has supplied the correct items.
  - Receiving Inspection
  - Installation reports

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ISO 9001:2000 QMS Requirements

7.5 Production & Service Provision

7.5.1 Control of Production & Service Provision

- Selection of the right suppliers
- Clarity of requirement

7.5.2 Validation of Processes for Production & Service Provision

- Unit testing, System Testing, Acceptance testing, Regression testing

7.5.3 Identification and Traceability

- Configuration management fulfils this requirement
  - Naming conventions, Version control, Config mgmt tool
  - Requirement traceability matrix

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ISO 9001:2000 QMS Requirements

7.5.4 Customer Property

- Activities involve items belonging to the Customer
  - Software, Hardware, VPN, Licenses, documents personnel, work place etc.,
  - Record the Customer property upon receipt,
  - Check that they are suitable for use.
    - If any problems are discovered, or not usable, report this back to the Customer for replacement.

7.5.5 Preservation of Product

- Configuration Mgmt tool for repository
- Build-Release process
- Regular Back-up, DRP/BCP;
- Protection from virus, theft, fire,

7.6 Control of Monitoring & Measuring Devices:

- Exclusion from QMS in Aurovision

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ISO 9001:2000 QMS Requirements

8. Measurement, analysis & Improvement

8.1 General

- Identify and plan your measurement/monitoring activities
- Enable improvements to processes & product
- Process for continually improving the QMS

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction

- Monitor information relating to Customer perception of how you meet their requirements
- Use this as inputs of the Management Reviews

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ISO 9001:2000 QMS Requirements

8.2.2 Internal Audit

- The standard requires that IQA are performed, so as to ensure that the QMS continues to meet the requirements of ISO 9001:2000
- A procedure for Internal Quality Audit is required

8.2.3 Measuring & Monitoring of Processes

- Metrics Program for measurable process parameters
- Collection, analysis and interpretation of Process data

8.2.4 Measuring & Monitoring of Product

- Defect management, defect tracking,
- Collection, analysis and interpretation of Product data

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ISO 9001:2000 QMS Requirements

8.3. Control of Nonconformity

- Ensure that any nonconforming items are not used or supplied accidentally
- A Procedure is required defining the steps to control non-conforming products in the project.
  - The source of the non-conformities can be reviews, testing, final inspection, audits, and/or customer complaints

8.4. Analysis of Data

- Collect and analyze relevant data in order to be able to ensure the suitability of the QMS
  - Customer satisfaction, conformance to Customer requirements, suppliers data
  - Improve the QMS based on learning

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ISO 9001:2000 QMS Requirements

8.5. Improvement

8.5.1 Continual Improvement

- Ensure that you take corrective and preventive actions from
  - The analysis of nonconformance, including audit reports (internal and external) and determination of consequential actions
  - Use and review of quality objectives
  - Analysis and review of levels of Customer satisfaction
  - Management Review of nonconformance, identification of external changes and planning of additional or alternative resources

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ISO 9001:2000 QMS Requirements

8.5.2 Corrective Action

- Procedure for identifying problems and taking corrective actions is required.
  - Defect data
  - Nonconformance
  - Issues

8.5.3 Preventive Action

- Procedure for identifying repetitive problems and taking preventive actions is required.
  - Defect Prevention
  - Prevention of NCs

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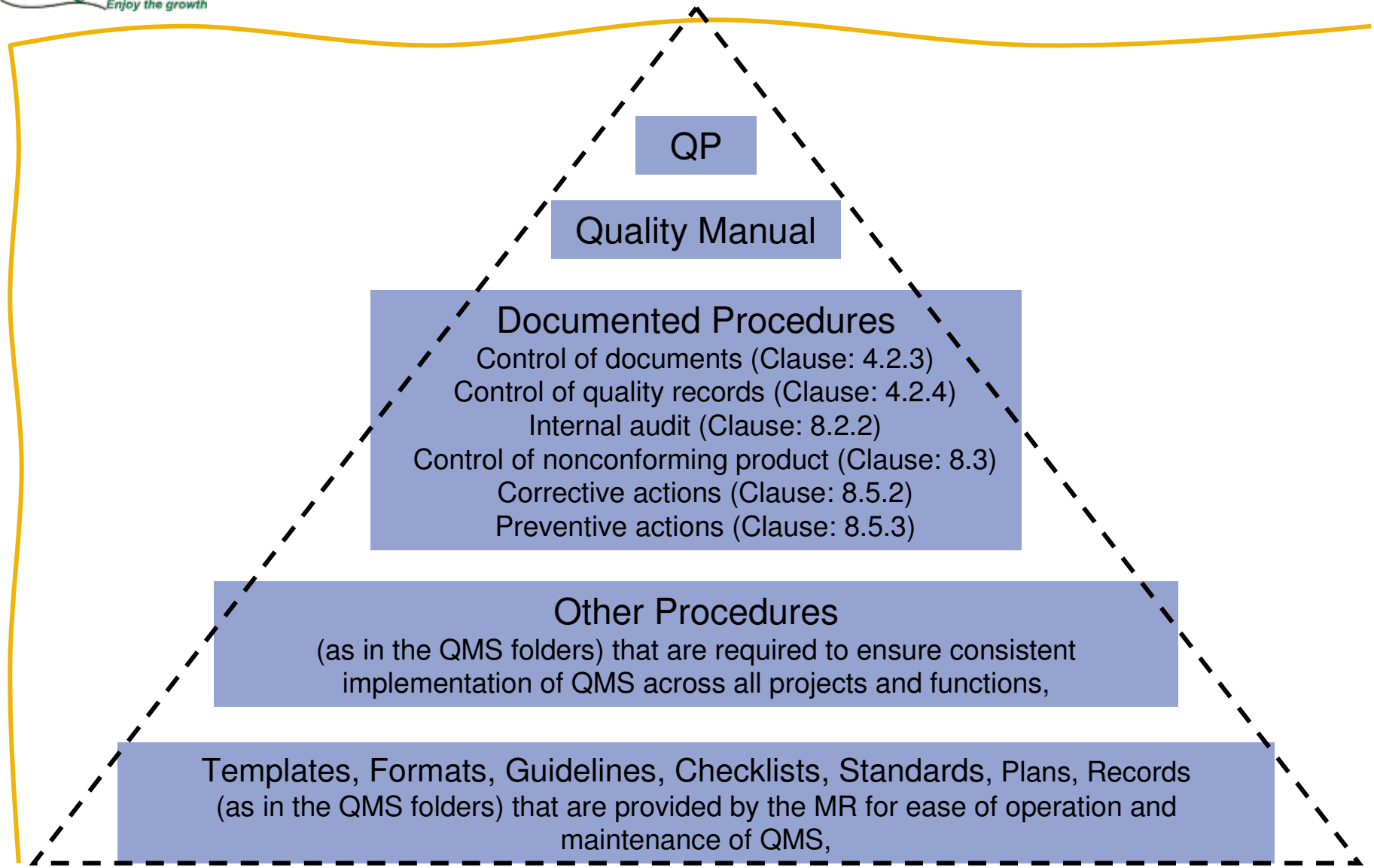
QMS Documentation Hierarchy



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DAY – 2

- Aurovision QMS
- The Audit Process
- Exercises
- Summary

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AUROVISION QMS

- Aurovision QMS

Aurovision QMS

- Aurovision QMS is organized in the following folder structure. This structure covers only the QMS documents and not the Records:
  - SEPG Documents
    - ISO_Document_ID
    - QM_PRC_COM01-Quality-Manual-V1[1].0
  - All Procedures
    - Engineering (ENG)
    - Process (PRC)
    - Project (PRJ)
    - Support (SUP)
  - All Templates
    - Engineering (ENG)
    - Process (PRC)
    - Project (PRJ)
    - Support (SUP)

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Aurovision QMS

- All Forms
  - Engineering (ENG)
  - Process (PRC)
  - Project (PRJ)
  - Support (SUP)
- All Standards & Guidelines
  - Engineering (ENG)
  - Process (PRC)
  - Project (PRJ)
  - Support (SUP)
- All Checklists
  - Engineering (ENG)
  - Process (PRC)
  - Project (PRJ)
  - Support (SUP)

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The Audit Process

- Clause 8.2.2 Internal Audit
- Internal audits Flow
- Internal audits
- What are the Auditors looking for?
- Nonconformity

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Clause 8.2.2 Internal Audit

- The organization shall conduct internal audits at planned intervals to determine whether the QMS
  - Conforms to the planned arrangements, to the requirements of this International Standard and to the QMS requirements established by the organization, and
  - Is effectively implemented and maintained.
- An audit programme shall be planned, taking into consideration the status and importance of the processes, areas to be audited, and the results of previous audits.
- The audit criteria, scope, frequency and methods shall be defined
- Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.
- Auditors shall not audit their own work

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Clause 8.2.2 Internal Audit

- The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

  4.2.4 Control of Records
  - Keep adequate records as evidence of QMS implementation
  - keep them for a defined minimum period (life)
  - Have proper and organized repository for the document in a way that they are easily accessible to relevant persons.

- The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.
- Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

Internal audits

Internal Audit Definition:

- A systematic and independent examination to determine whether Qualities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives
- Internal audits are carried out by your own trained personnel.
- Internal quality audits examine the elements of a quality management system in order to evaluate how well these elements comply with quality system requirements.

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Internal audits

- Registration to ISO 9001:2000 requires company periodically go through two types of audits:
  - Third-party audits (audits by the registrar),
    - audit has a pass/fail result
    - determine should become (or stay) registered to ISO 9001.
    - tell what's wrong with the system, but not "how" to fix them.
  - Internal audits (self-audits by the company).
    - to make the QMS work better for everyone,
    - catch problems before your customer or registrar does.
    - free to ask the auditors for help in case of Non-conformances
    - Identify problems with the quality management system, not with the people who are carrying it out

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Internal audits

- Third-party audits (audits by the registrar),
  - Certification Audit
    - First time Certification Audit and
    - Recertification Audits every 3 years
  - Surveillance Audit
    - Audits conducted every 6/9/12 months by the Certifying agents.
    - To ensure that the system still complies with the requirements to which it refers.
    - Re-audit outstanding non-compliances to ensure effectiveness of corrective actions
      - Frequency depends on size and type of organization and also the past records of audit findings.

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Internal audits

- Audit Types
  - Compliance Audit or Documentation Review
    - To determine the extent to which the documented QMS meets the requirements of the ISO 9001:2000 Standard
      - Quality Manual, Mandatory procedures, interrelationship with various other procedures
    - Carried out in advance of certification audit.
      - Done independently by the Third party auditor
      - Referred to as Desk-top audit due to the nature of audit
  - Conformance or Implementation Audit
    - To determine if the QMS is implemented effectively
    - Identify any non-conformances and report the same
- Audit Frequency
  - Certification Audits: Every three years
  - Surveillance Audits: Once in 6 months or 1 year.
  - Internal Audits: Once every 3 months.

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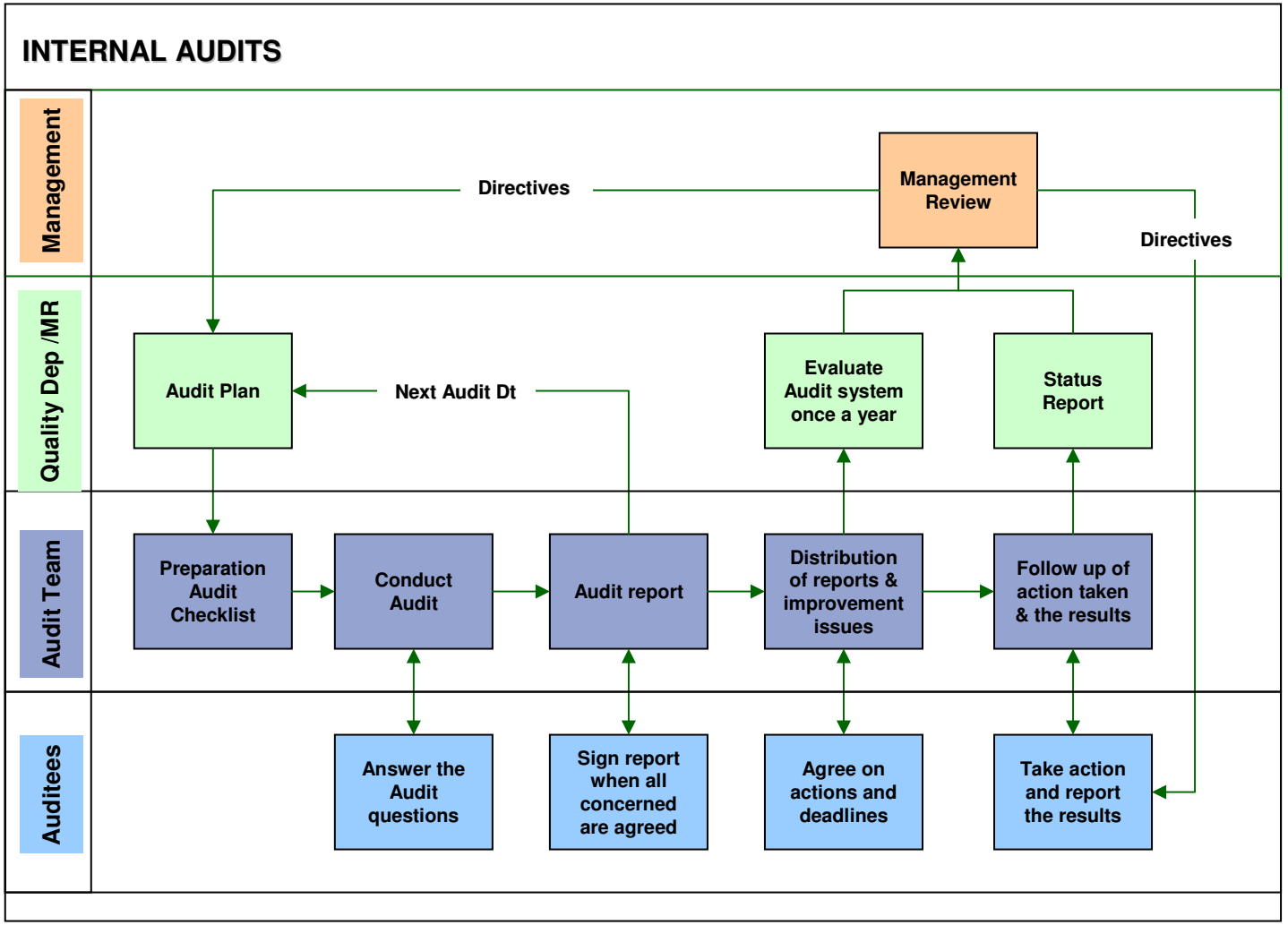
Internal audits Flow



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Internal audits

- Audit Cycle:
  - Planning The Audit
  - Conducting The Audit
  - Reporting The Audit
- Planning The Audit
  - Audit Brief Identified
  - Auditee contacted. Relevant information obtained
  - Audit planned and confirmed with Auditees and Auditors
  - Audit Team briefed

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Internal audits

- Responsibility
  - MR:
    - Planning an IQA
    - Annual Plan
    - Audit Schedule for a specific audit
      - Project/Function, Date, Time, Name of Auditee, Name of Auditor, Venue etc.,
    - Announcing the audit schedule to Auditees & Auditors
      - At least 1 week in advance; Give time for the Auditee to get organized and be available for audit
    - Coordinate with the Auditors & Auditee
      - Opening/Closing meeting
      - Ensure audit happen as per schedule
    - Prepare Audit Report
    - Monitor closure of NCs
    - Conduct MRM with Sr. Mgmt

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Internal audits

- Responsibility
  - Internal Auditors:
    - Study the system to be audited
      - Projects/Functions, Processes in the QMS
    - Prepare Audit checklist
      - This may be done one time and used again
    - Attend Opening/Closing meetings
    - Perform Audit as per the schedule
      - Fact finding and not fault finding
    - Take notes
    - Identify NC
    - Prepare NC reports
      - Use the standard format, hard copies, signed by Auditee, Auditor
    - Verify closure of an NC

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Internal audits

- Conducting The Audit
  - Opening Meeting held
    - Convened by MR
    - Attended by Sr. Mgmt, All Auditees, All Auditors
    - Short meeting,
  - Auditors follow through trails
    - As defined in schedule
  - Follow-up
    - MR does regular short Meetings with Auditors and Auditees to ensure the activities are going as per the schedule

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Internal audits

- Reporting on an Audit:
  - Nonconformity's defined and analyzed for trends
  - Report prepared detailing results and conclusions
  - Presentation of findings in Closing Meeting
  - Conduct follow-up actions

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Internal audits

- Auditing Skills:
  - Be factual / objective
  - Be clear and concise
  - Give clause number of quality standard / company document
  - Define the exact instance
  - Be locatable by other auditors

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Internal audits

- Auditing Skills:
  - Communication skills :
    - Verbal, Body language, Style and sound of speech, facial
  - Assertive Behavior :
    - Standing up for your rights,
    - Not violating the rights of others,
    - Expressing your needs, wants, views and feelings
  - Put people at ease :
    - Be open in speech and manner
    - Be calm, cool and objective
    - Be assertive
    - Smile and use humor only when appropriate
    - Don’t infringe “personnel space”

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Internal audits

- Auditing Skills (Contd.):
  - Feedback by auditor :
    - Generate questions from what they say
    - Look interested
    - Gently steer them
  - Look for :
    - Signs of stress
    - Symptoms of lying or conflict
    - Signs of hostility or defense

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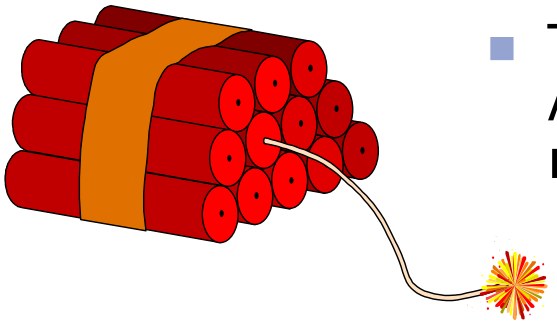
Internal audits

- Auditor's Tool Kit:
  - Copy of standards
  - Checklists
  - Report forms
  - Audit plan

- Warning!
  - The auditor must take special care :
    - To avoid sounding like an interrogator
    - To remain objective, calm, friendly
    - To remember that 80% of the task is listening
  - Take care to prevent Auditee talking too much (Time wasters)



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What are the Auditors looking for?

Auditors Look at:

- Look at a sample of the quality management system.
  - No time to look at everything in the company that affects quality,
- Try to pick out the more important activities
- Verify areas that had problems in the past to see how they are improving.
- Documents; and talking to people about how they use the documentation and carry out their work.

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What are the Auditors looking for?

- Look for Evidence
  - that the system (as documented) meets the requirements stated in ISO 9001.
  - that all employees understand the documentation that affects them.
  - that the system (as implemented) works according to planned arrangements (such as the instructions stated in your quality management system documentation or in agreements with customers).
  - that the system is effective in providing quality products and services.
- Evidence auditor finds might be in the form of:
  - Something the auditor sees.
    - For example: out-of-date documentation

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Nonconformity

- Nonconformities report:
  - What is the problem?
    - Describe clearly, concisely and factually;
    - Factual, understandable and traceable
  - Why is the noncompliance?
    - Against what requirement?
    - Give clause number of quality standard
    - Give the reference to company document
  - Where did it occur?
    - Which department, function or activity?
  - Who? - avoid apportioning the blame
    - Avoid naming any individual

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Nonconformity

- Observation:
  - Notes taken by the auditor during the audit provide the objective evidence while raising an NC.

- Aurovision QMS ref:
  - Internal Audit Report
  - Internal Audit summary report
  - List of Internal Auditors
  - Internal Audit Schedule
  - Sample NC Report format
  - Sample Audit Report Format
  - Analysis of NCs

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Nonconformity

- Nonconformity
  - The non-fulfillment of specified requirement
- Minor Nonconformity
  - Either a failure of meeting one requirement of a clause or other reference documents OR a single observed lapse in following one item of a company procedure
- Major Nonconformity
  - The absence or the total breakdown of a system to meet the requirements of a clause of ISO 9001 or other reference documents.
- A number of minor NC's against one clause can represent total breakdown of a system and thus can be considered a major NC

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Nonconformity

- Observation
  - A statement of fact made as part of the audit process and substantiated by an objective evidence
- Objective evidence
  - Qualitative or quantitative information, records or statements of facts, pertaining to the quality of an item or service or to the existence of a quality system element which is based on the observation, measurement, or test and which can be verified

OR

  - A factual statement that can be verified. Not based on opinion, preference or emotions. Based on actual observation and statements

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Nonconformity

- Points to bear in mind:
  - Are there other similar non-compliance?
  - Has the root cause been addressed?
  - Has the likelihood of recurrence been assessed?
  - Have they followed the CA procedures?
  - Is a track of all corrective actions being maintained?

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Exercises

- 100% inspection
- Nonconformance observation samples
- Quiz

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100% inspection

- Instructions:
- 1. Go through the material and count the ‘f’s, both small and capital letters.
- 2. Do not go through the material a second time as that would be 200% inspection, not 100%.
- Time to inspect: 30 Sec

The necessity of training farm hands for first class farms in the fatherly handling of farm live stock is foremost in the minds of farm owners. Since the forefathers of the farm owners trained the farm hands for first class farms in the fatherly handling of live stock, the farm owners feel they should carry on with the family tradition of training farm hands of first class farms in the fatherly handling of the farm live stock because they believe it is the basis of good fundamental farm management.

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Discussions on NCs

- QAP1 requires that the Quality Director attends at least four Quality meetings for each department in a one-year period. However, Gita Gupta was not at the Operations Department quality meetings between June and October 2006, as shown by the meeting minutes
- The Project file for the HST project showed all detailed design tasks to be completed. However, a member of the design team was writing chapter 10 of the design specification.
- A Programming Team Leader for the GOSIP project was unable to find any record of design review for the project which was now in system test.

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Quiz

1. During an internal audit, a department or functional group within an organization is evaluated according to every applicable clause of the quality system standard.
    - True
    - False
2. It is usually most appropriate for an individual who works within a department to conduct an internal audit of that department.
    - True
    - False

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Quiz

3. A variety of media may be used as documentation of an organization's quality system.
   - True
   - False

4. An audit that can help customers develop criteria for selecting, grading and approving suppliers is called a:
   a) First party audit
   b) Second party audit
   c) Third party audit

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Quiz

5. An audit that may result in achieving quality system registration is called a:

    a) First party audit

    b) Second party audit

    c) Third party audit

6. The purpose of an internal audit is to identify weaknesses in a quality system, address them and follow up to be sure that corrective actions are effective

    - True
    - False

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Quiz

7. During an audit, the auditor should try to ask open-ended questions:
   - True
   - False

8. It's recommended that auditors share their findings with Auditees on a regular basis throughout the audit instead of waiting for the final reporting
   - True
   - False

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Quiz

9. Nonconformity exists when the implemented quality system is not effective; for instance, if established procedures for detecting unacceptable product do not work consistently:
   - True
   - False

10. Comments made by one employee about another employee's actions are sufficient evidence of nonconformity
   - True
   - False

Quiz

11. The auditor's job is complete when the closing meeting is concluded:
    - True
    - False

12. ISO 9001:2000 Registration is valid for ….
    - One year
    - Five years
    - Three years

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Quiz

13. Internal audits can be done before certification audit:
    - True
    - False

14. The Internal Auditors report to MR
    - True
    - False

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Quiz

15. Quality System Audits are used to verify:
    a) That all suppliers to the Org. are ISO 9000 certified
    b) The extent to which audit criteria are fulfilled
    c) The number of persons working on a contract
    d) All of the above

16. In preparing for an audit, it is important to
    a) Plan
    b) Define the scope of the audit
    c) Select a lead assessor and competent team
    d) All of the above

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Summary

- PDCA Cycle
- Critical Success Factors
- Critical Barriers

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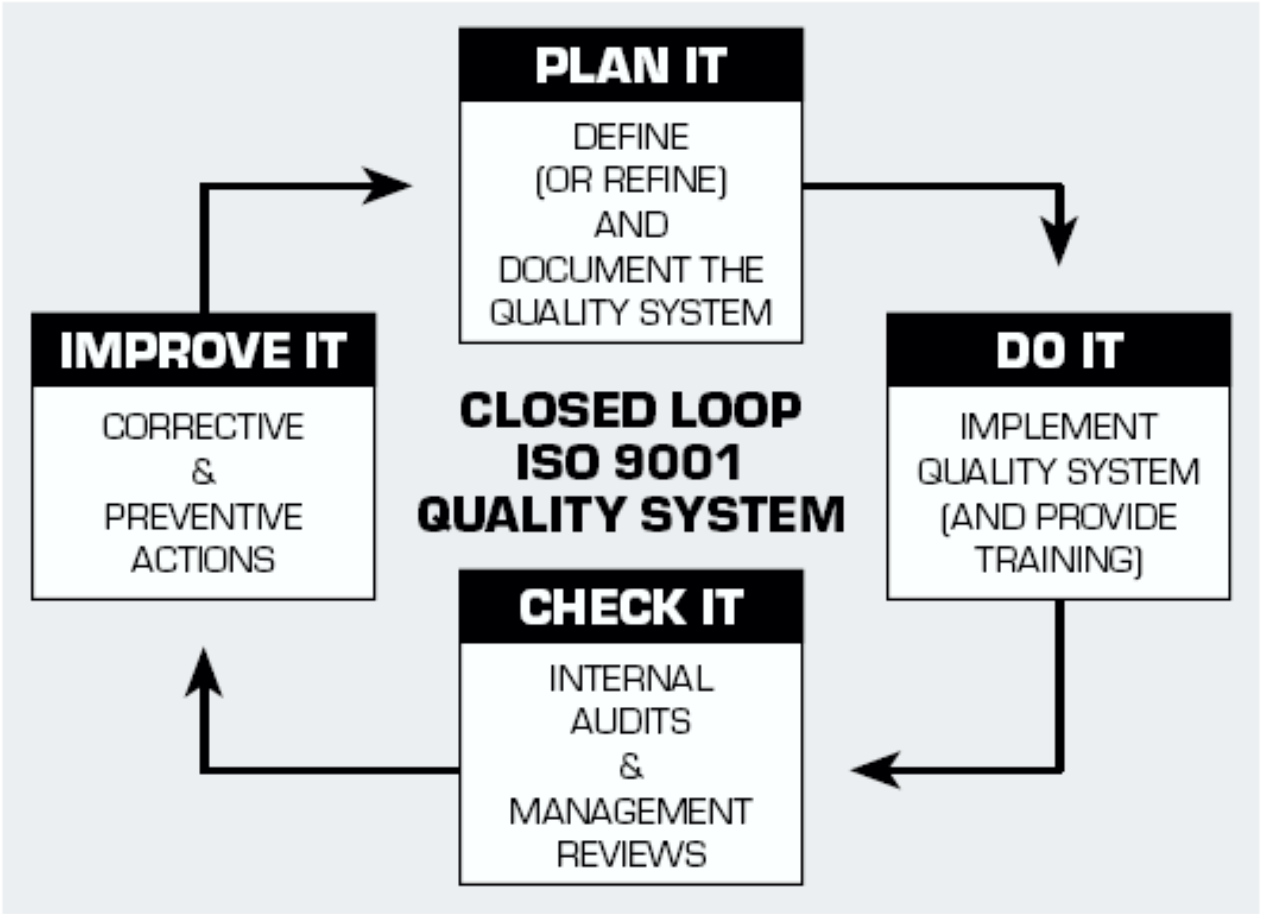
PDCA Cycle



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Critical Success Factors

- Senior management commitment;
- Training and mentoring
- Setting achievable goals
- Awareness of Software Processes among teams
- Adequate staff time and resources; Staff involvement
- Formal methodology; experienced staff
- Encouraging communication and collaboration
- Timely issue resolution & Risk mitigations
- Facilitation by experienced consultants

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Critical Barriers

- Lack of sponsorship
- Lack of support/management commitment
- Organizational politics
- Lack of awareness
- Lack of resources
- Time pressure; Post delivery documentation
- Lack of funding

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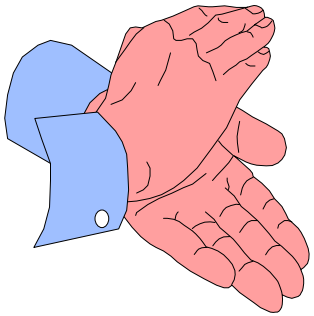
Don't give up five minutes before the miracle!

- Frank Dabney

Any Questions?



Contact Information

M V Muralidharan
Director – Operations
muralim@eprama.com

B-610, Kanara Business Centre
Ghatkopar – Andheri Link Road
Ghatkopar (East), Mumbai – 400 075
Phone: 982051895
URL: www.eprama.com ; Email: info@eprama.com