
Audit Techniques & Practices for Regulators
RCA
QA
SMS
ISO
INTRO
DIVING IN
AUDIT ROADMAP


INTRO


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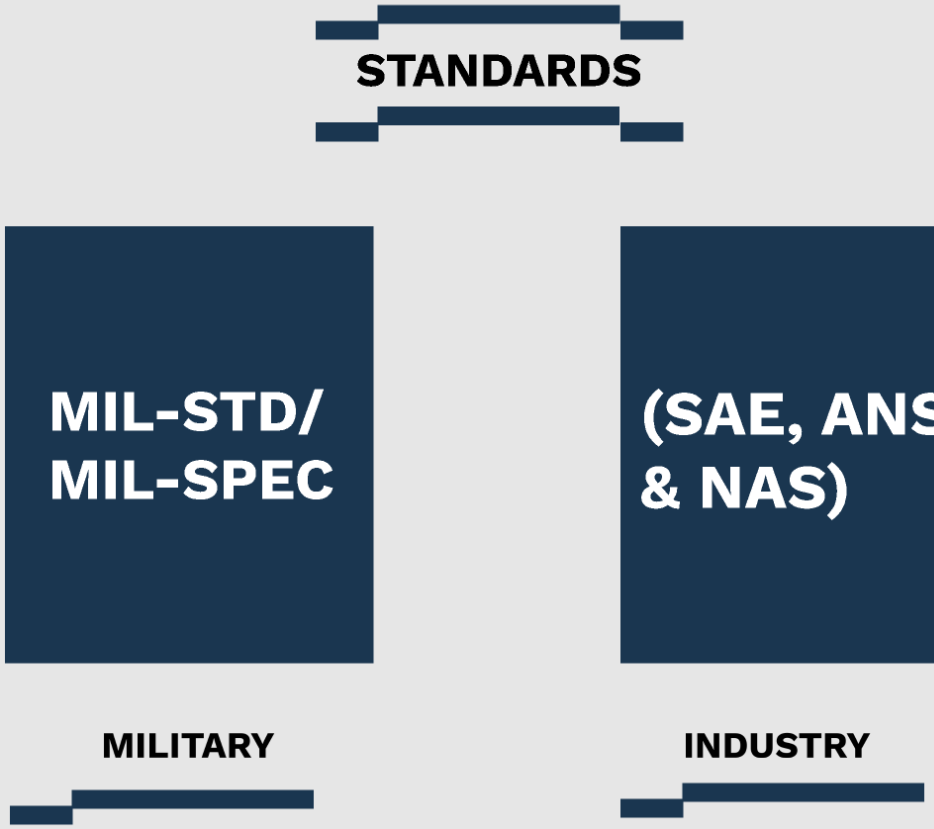
In the beginning
DIVING IN
QC/QA, ISO etc.
TRAINING TOPIC 1
TRAINING TOPIC 2


STANDARDS
MIL-STD/
MIL-SPEC
(SAE, ANSI
& NAS)
MILITARY
INDUSTRY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Quality can be described in a number of different ways depending on the perspective and the product or process involved.

Quality is defined as "an inherent feature, a degree of excellence, having certain properties and grade." Webster's Dictionary defines quality control as "an aggregate of activities (as design analysis and statistical sampling with inspection for defects) designed to ensure adequate quality especially in manufactured products."

While quality means different things to different people, AMTs should define quality as a collection of processes designed and implemented to ensure adequate quality exists in both aviation maintenance processes and products.

Let's go back a few years to the time when Quality Control (QC) was introduced as a product-oriented concept.

Picture an inspector sitting at the end of an assembly line looking at each widget as it came down the chute. Inspectors looked for obvious defects and checked dimensions with some sort of "go/ no-go" gauge.

The aviation equivalent would be a team of inspectors in a large operation, or an IA inspecting an aircraft after a major repair or phase inspection.

This type of inspection looked at the finished product with little emphasis on the process that produced that product.

Depending on the "product," this system worked quite well for a long time, but as manufacturing complexity evolved, end of assembly line inspection was not sufficient.

Into that equation was also thrown cost, economies of scale, new materials, and new manufacturing processes.

One component of a quality management system is Quality Assurance (QA), and is most closely identified with ISO-9000 and its successors.

It is a process-based system that places more emphasis on how something is made rather than the final product.

Statistical process control has become the standard for manufacturing operations that use high technology machinery, and this quality process has been applied to the balance of quality programs in many different industries.

How does it apply to aviation?

How do new quality assurance processes apply to the aviation industry?

It has been more difficult to apply these principles to aviation, mainly because of the small numbers of aircraft and components relative to other manufacturing processes for which quality assurance was originally designed.

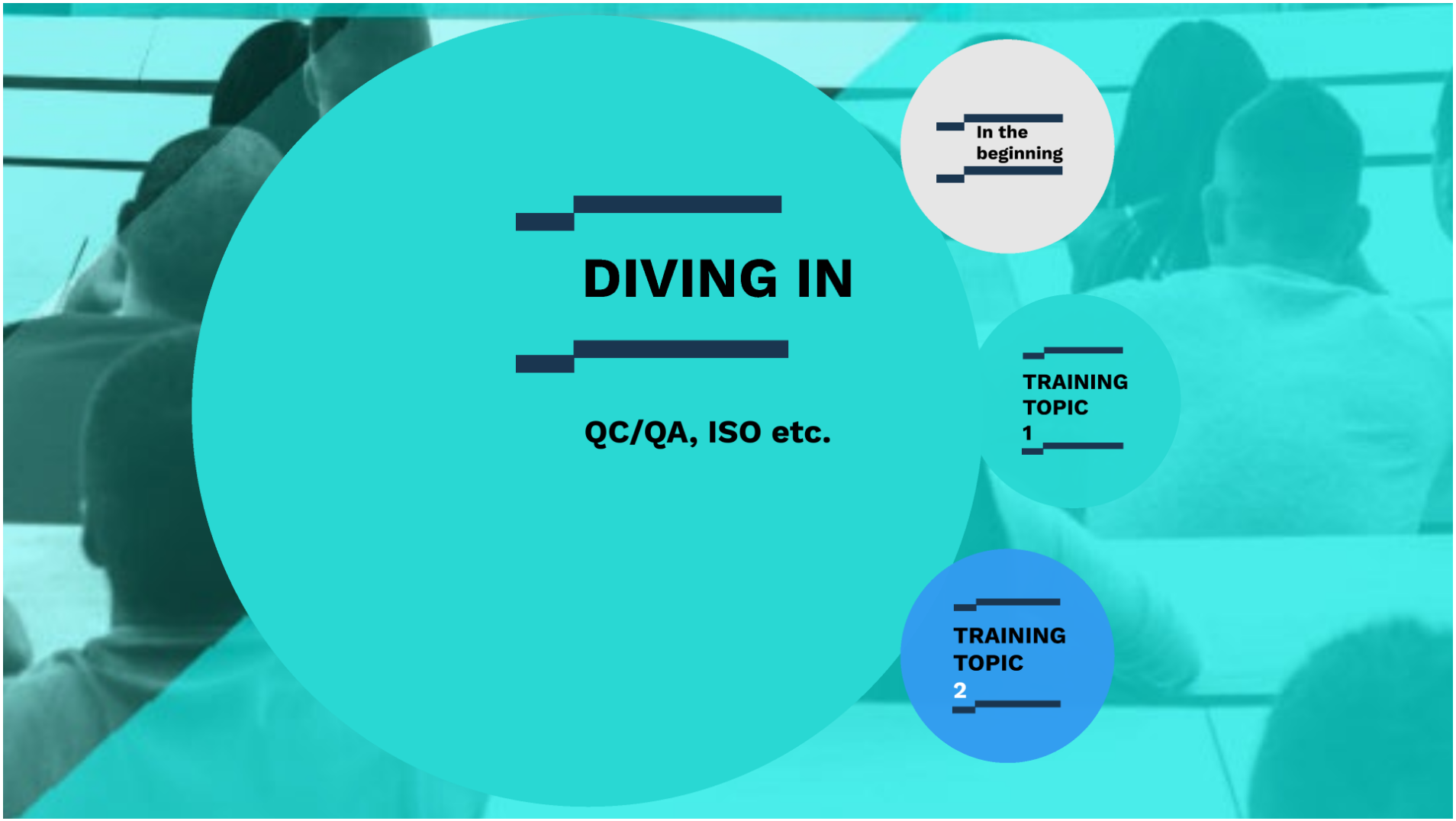
It has been relatively easy to apply these principles to the aircraft manufacturing process because of the intense automation and use of computers in the industry.

One problem remains however, and that is that aircraft are still pieced together by hand, despite the assembly line appearance of aircraft factories.

And how does the quality assurance process apply to aviation maintenance?

This is more difficult to answer because aviation maintenance is governed by several factors:

- **statutory requirements (the FARs),**
- **original equipment maker (OEM) maintenance schedules and requirements (aircraft maintenance manual),**
- **industry standards and specifications (SAE, ANSI, NAS), and**
- **general maintenance practices (AC 43.13-1B, 337 and field approvals, etc.).**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In The beginning -
The Start
QA VERSUS QC


From Medieval
Times


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…..then to simplify and speed up this process without compromising safety, the military began to use sampling techniques for inspection, aided by the publication of military-specification standards and training courses in Walter Shewhart's statistical process control techniques.


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World War II and Quality

Fast Forward…

The birth of total quality in the United States came as a direct response to the quality revolution in Japan following World War II. The Japanese welcomed the input of Americans Joseph M. Juran and W. Edwards Deming and rather than concentrating on inspection, focused on improving all organizational processes through the people who used them.


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By the 1970s, U.S. industrial sectors such as automobiles and electronics had been broadsided by Japan's high-quality competition. The U.S. response was to implement TQM (Total Quality Management) which would embrace the entire organization as well as statistics.


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Beyond TQM – Quality Today

Since the turn of the century quality improvement has matured significantly.

New quality systems have evolved from the foundations of Deming, Juran and the early Japanese practitioners of quality.


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Quality has moved beyond manufacturing into service, distribution, healthcare, education and government sectors.

Quality is easily recognized in some of these terms: ISO 9001:2000, AS9100, ISO 13485, ISO 14001, ISO 17025, TS16949, Six Sigma, 5S, Lean Manufacturing, Reorganization, CE Mark, UL, and more.


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Summary

* Quality is not new.
* ISO is headquartered in Geneva.
* ISO Standards are in all industries.

- ISO and quality blossomed in the WW II effort.
- Global Pressure forced the U.S. into TQM


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Summary

Without standards, the goods we buy would probably be unsafe and incompatible.

- Quality is not FREE, but it is good.
- Quality and ISO 9000 are most likely here to stay.


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For more information

The following websites ar an excellent source of info…

International Organization for Standardization – www. iso.org

American Society for Quality – www.asq.org

Quality Digest Magazine – www. qualitydigest.com

Worldwide Quality Network – www.wqntoday.com


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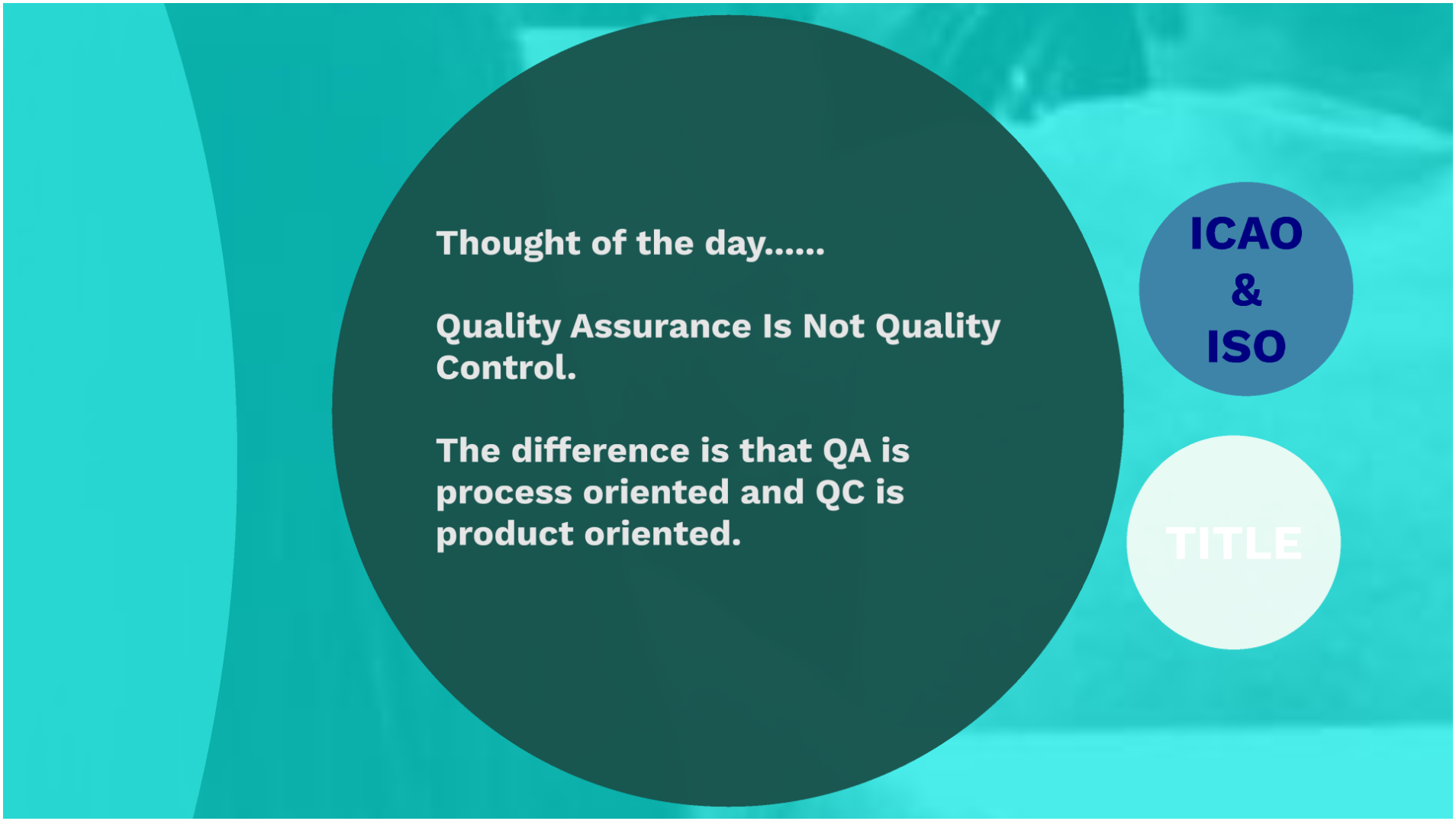
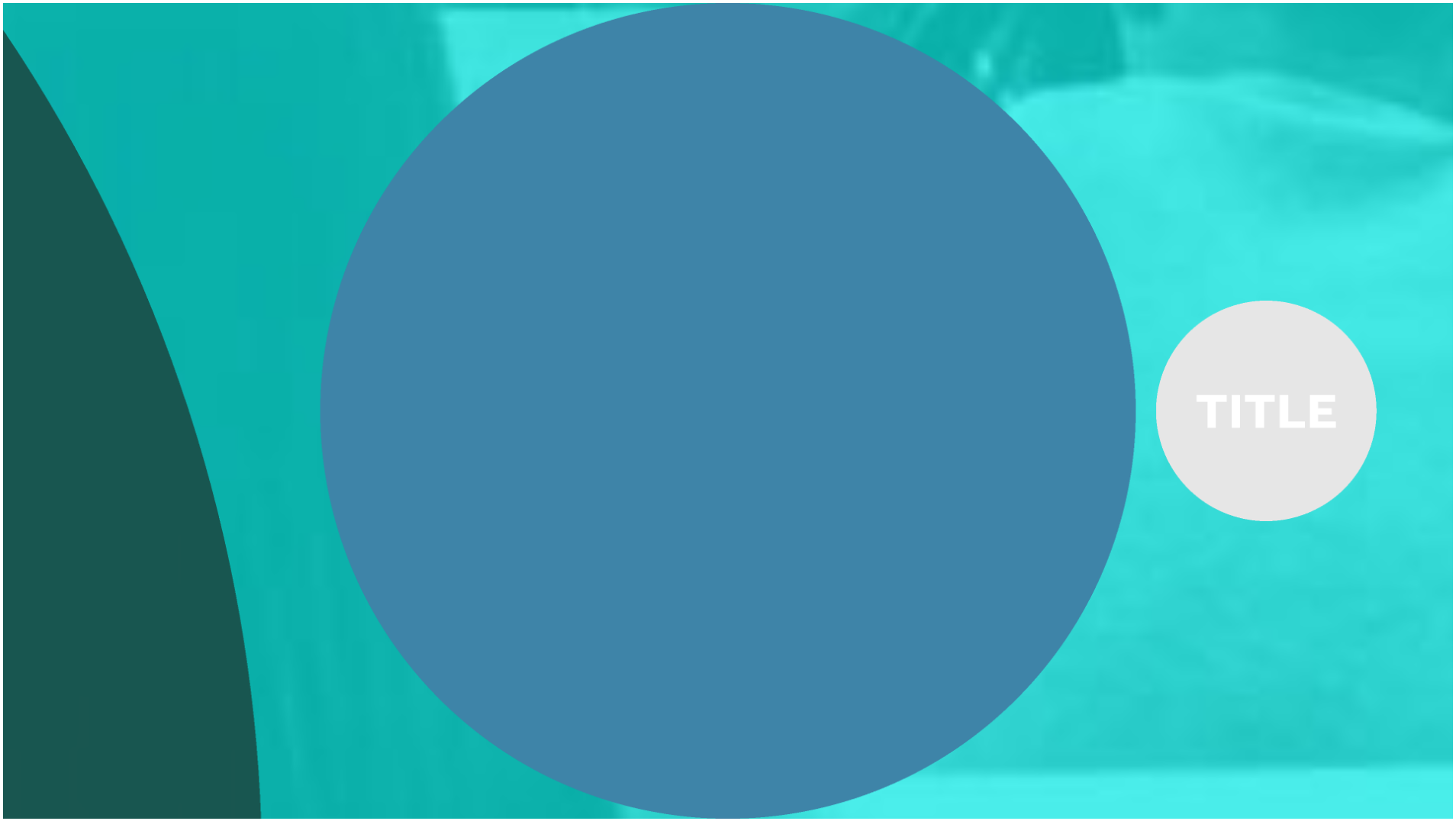
ISO standards contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner.
They make trade between countries easier and fairer.
ISO makes the world better
They provide governments with a technical base for health, safety and environmental legislation.
They aid in transferring technology to developing countries. ISO standards also serve to safeguard consumers, and users in general, of products and services, as well as to make their lives simpler.
The new organization, ISO, officially began operations on 23 February 1947.
ISO is a network of the national standards institutes of 156 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. (http://www.iso.org)
What does ISO do?
The International Standards which ISO develops are very useful.
They are useful to industrial and business organizations of all types, including governments and other regulatory bodies.
In The Beginning....
The quality movement can trace its roots back to medieval Europe, where craftsmen began organizing into unions called guilds in the late 13th century.
Many people are involved
When things go well - for example, when systems, machinery and devices work well and safely - there it is because they conform to standards.
And the organizations responsible for many thousands of the standards which benefit society worldwide is ISO.
In The Beginning....
This model was followed until the early 19th century when factories came to be and there was more emphasis on product inspection.
In the early 20th century manufacturers began to include quality processes in quality practices.
The Early Days
In 1946, delegates from 25 countries met in London and decided to create a new international organization, of which the object would be "to facilitate the international coordination and unification of industrial standards".
What does ISO do?
Additionally it applied to trade officials, to conformity assessment professionals, to suppliers and purchasers in industry, business in both public and private sectors, and, ultimately, to people in general in their role as consumers and end users.
World War II and Quality


From Medieval
Times


In The beginning -
The Start
QA VERSUS QC


Thought of the day.....
Quality Assurance Is Not Quality Control.
The difference is that QA is process oriented and QC is product oriented.
ICAO & ISO
TITLE


TITLE


The Elements
of Safety
Building
a
QMS

INTERNATIONAL CIVIL AVIATION ORGANIZATION

AIM - QMS

QMS requirements and the approach of an external auditor.

1

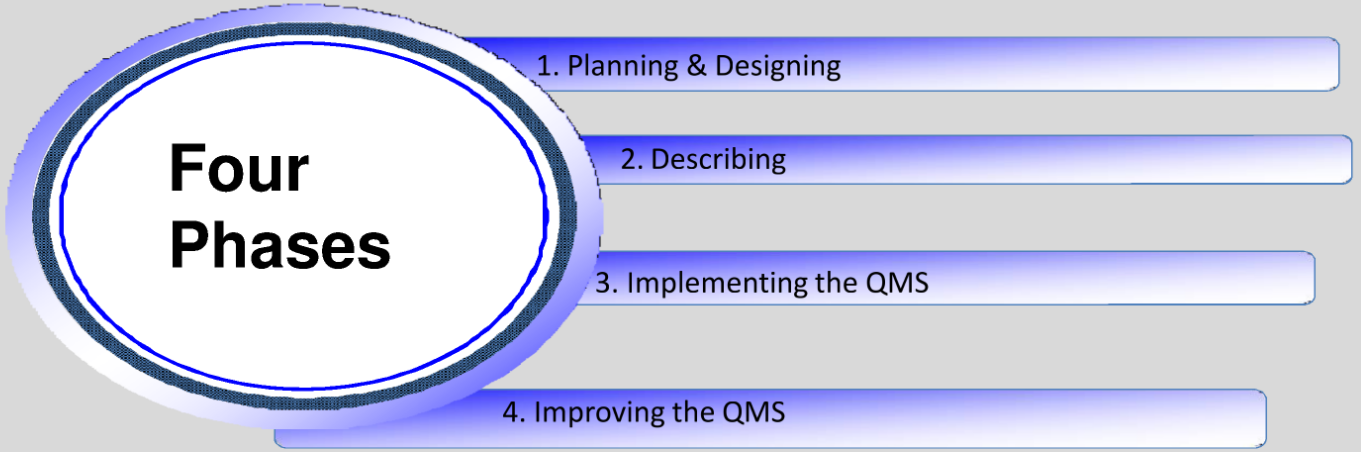
INTERNATIONAL CIVIL AVIATION ORGANIZATION

AIM - QMS

QMS requirements and the approach of an external auditor.

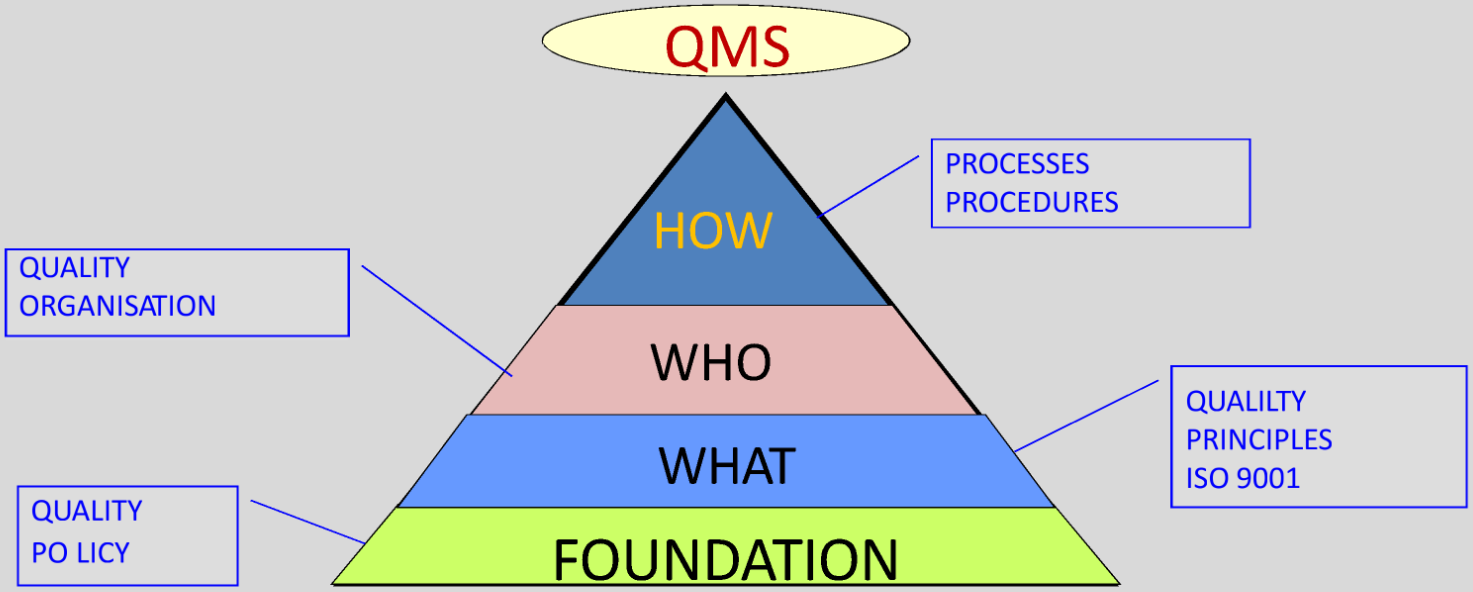
1

HOW TO IMPLEMENT A QMS?



2

THE FIRST STEPS



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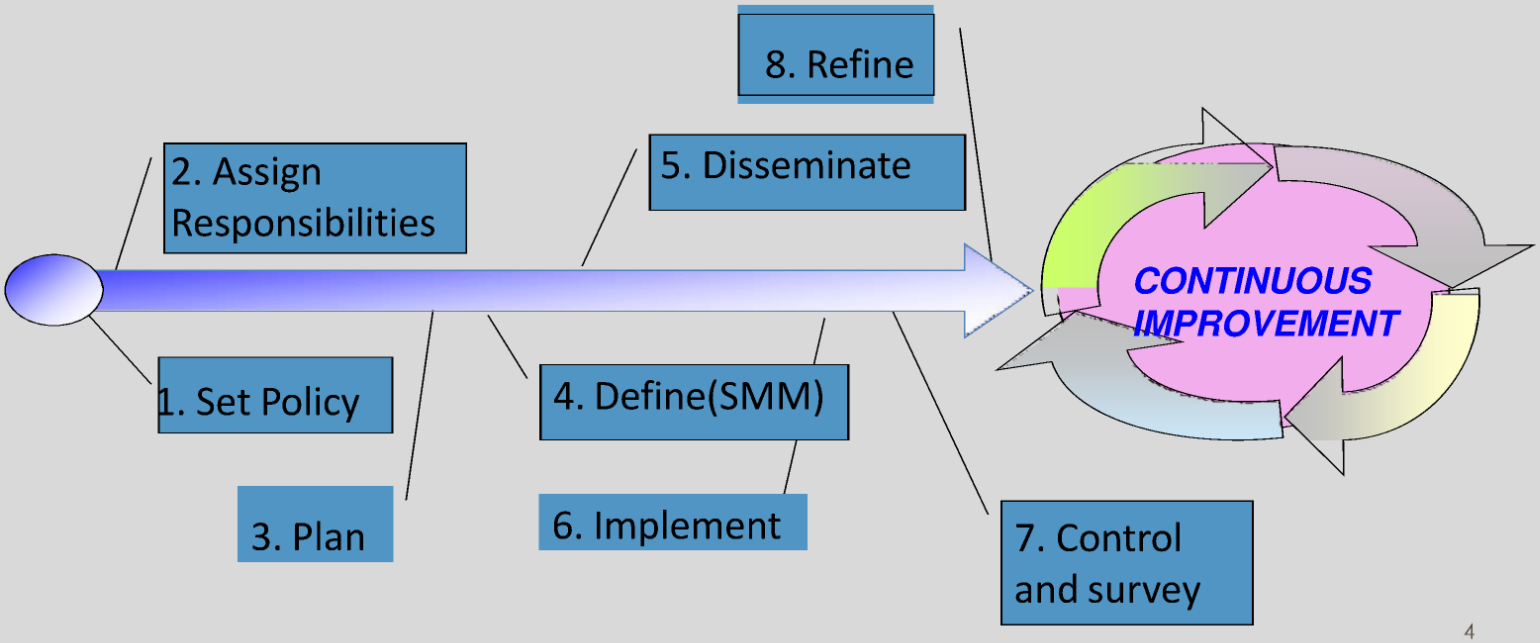
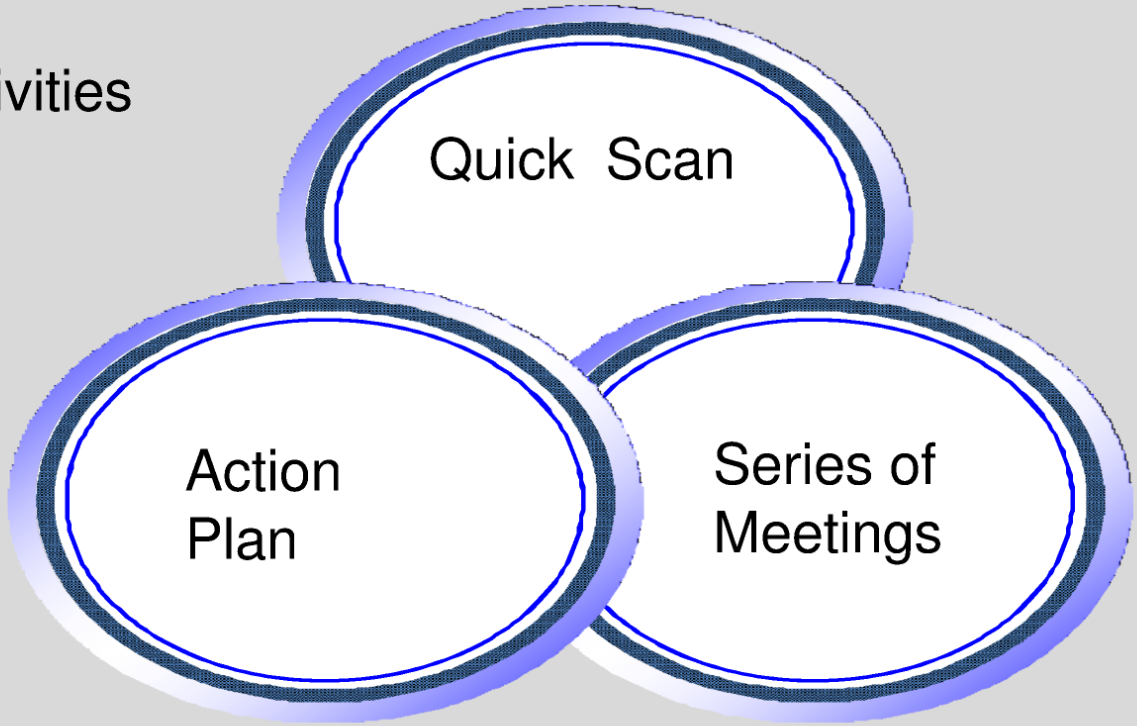
ONE POSSIBLE APPROACH



4

Planning and Designing Phase:

Activities



5

INITIAL SURVEY

Start by reviewing the current situation

- What elements of a QMS are already in place?
  - Organisation charts
  - Process documents
  - Forms and records
  - Job descriptions

6

IDENTIFY MISSING ELEMENTS

- Identify the items required that are not in place, these may be for example:
  - some process documents
  - some necessary records
  - an internal quality audit process
  - a formal management review process
  - a continual improvement process
- In effect you are performing a “Gap analysis”

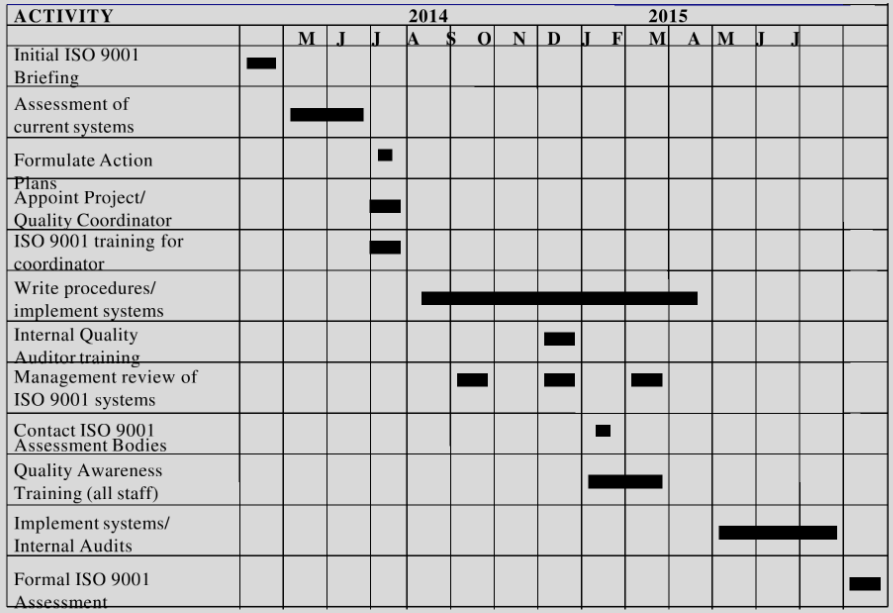
7

IMPLEMENTATION PLANS

- In order to ensure a successful implementation it must be planned, e.g. as a project:
- Resources must be identified
- Activities planned and assigned
- Time scales agreed and documented
- Responsibilities allocated
- Progress must be regularly monitored

8

Typical ISO 9001 Action Plan



DESCRIBING PHASE:

ACTIVITIES

Interfaces Check	Detailed Description
Process Improvement	Design of New Processes

10

QMS FRAMEWORK

The framework of the Quality Management System starts **with Top Management**:

- they set the business objectives
- they must then establish an organisation to put those policies into action
- they must ensure that key processes are controlled
- they must identify responsibilities and interfaces
- they must ensure that resources are provided

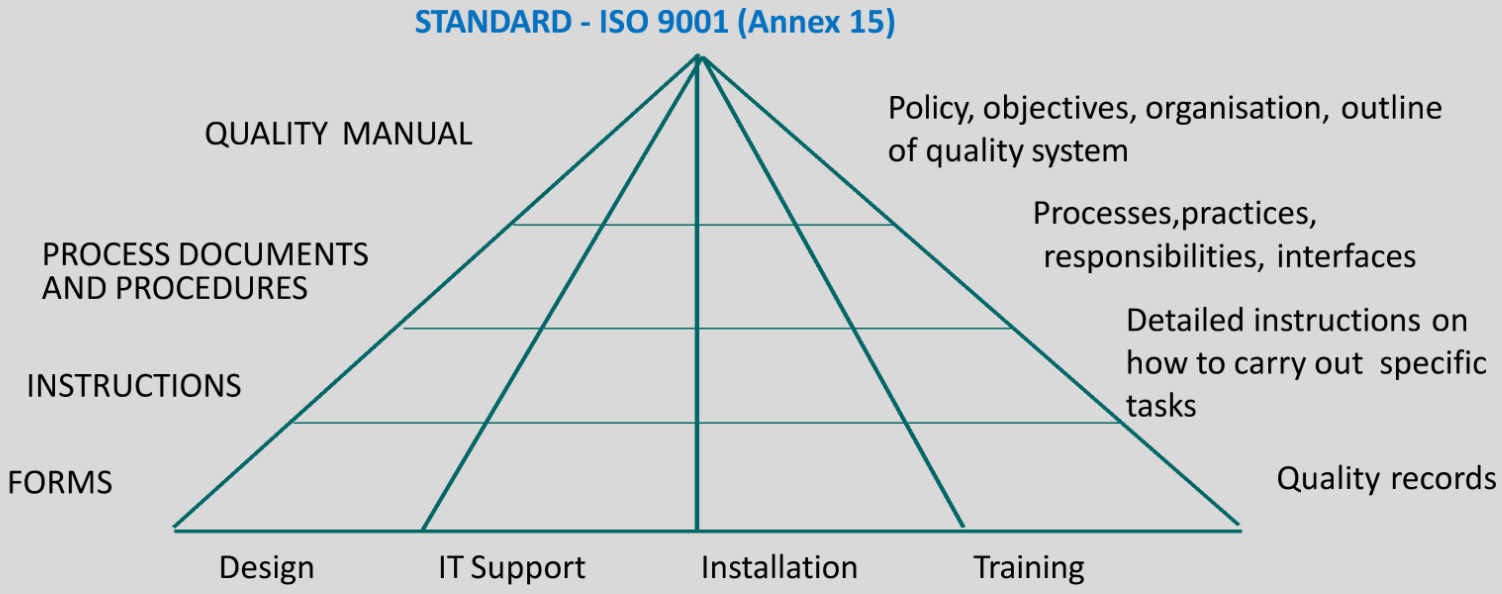
11

SYSTEM DOCUMENTATION

- The framework of the system documentation will depend upon the **business structure**, e.g.
  - The **size and complexity** of the organisation
  - Is there a department or team-based structure?
  - A typical documentation structure is shown on the next slide.

12

TYPICAL QMS STRUCTURE



13

DOCUMENT FORMAT

ISO 9001:

"The documentation may be in any form or type of medium"

- Therefore it could be in text form or in the form of process maps/flowcharts
- It could be a paper-based system or could be on computer, e.g. accessed via an intranet browser

14

CHOOSING A FORMAT

- Each organisation can choose its own format
- The majority at present have paper-based text documents
- Increasingly organisations are using flowcharts and “computerised” systems
  - a computer based solution often has advantages when it comes to document and change control

15

IMPLEMENTATION PHASE:
ACTIVITIES

16

PRODUCING THE QMS DOCUMENTATION

THE QUALITY MANUAL

- Description of the organisation
- Quality Policy, key objectives
- Structure of the organisation
  - ▶ Interfaces, responsibilities
- Overview of the Quality System
  - ▶ show approach to Standard requirements
  - ▶ detail and justify any exclusions

17

PRODUCING THE QMS DOCUMENTATION

PROCESS Documents

- Do we need process documents?
- The ISO 9001 standard calls for few mandatory procedures
- The question is do we need documents in order to effectively control our business processes?

18

PRODUCING the QMS Documentation

BENEFITS OF PROCESS DOCUMENTS

- Provide consistency/repeatability
- Define responsibility/authority
- Continuity when staff change
- Assist in staff training
- Help identify cause of errors
- Benchmark for improvement

19

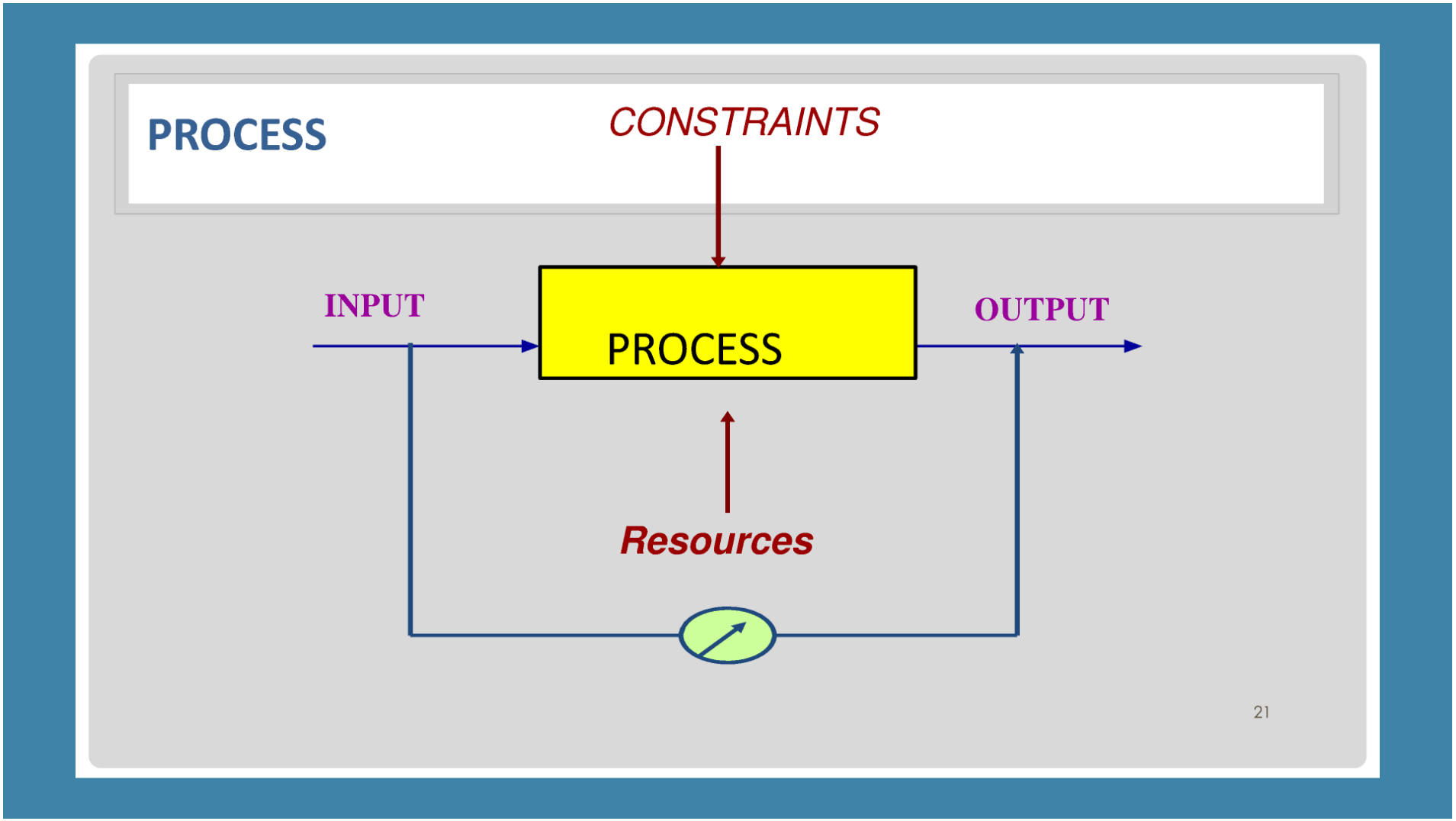
PROCESS

Definition:

Set of inter-related or interacting activities which transforms inputs into outputs

ISO 9000

20


PROCESS
CONSTRAINTS
INPUT
PROCESS
OUTPUT
Resources
21

PROCEDURE

Definition:

Specified way to carry out an activity or process

ISO 9000

i.e. describes how a process is performed

22

PROCEDURE DEVELOPMENT

- Establish current practice
- Document current practice
- Review current practice
- Prepare procedure
- Review and approve
- Issue procedure

23

PRODUCING PROCEDURES

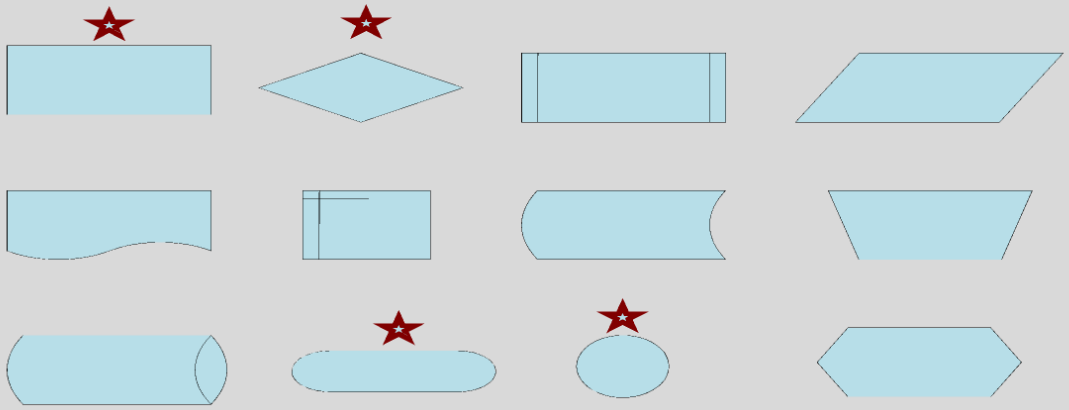
- Establish standard format/template
- Indicate approval/revision status
- Consider using flow charts or process maps
- Train the procedure writers

24

FLOWCHART

Using a flowchart is a very effective way to describe a process
“a picture is worth a thousand words”

SYMBOLS

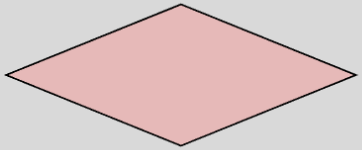


25

FLOWCHART SYMBOLS

Any process can be represented in the form of a simple flow chart using just two symbols:

Activity or process

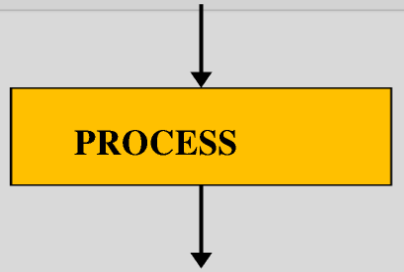


Decision

26

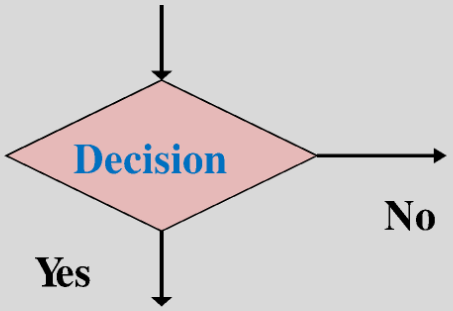
FLOWCHART RULES

There is one route into the box and only one route out for the process activity boxes



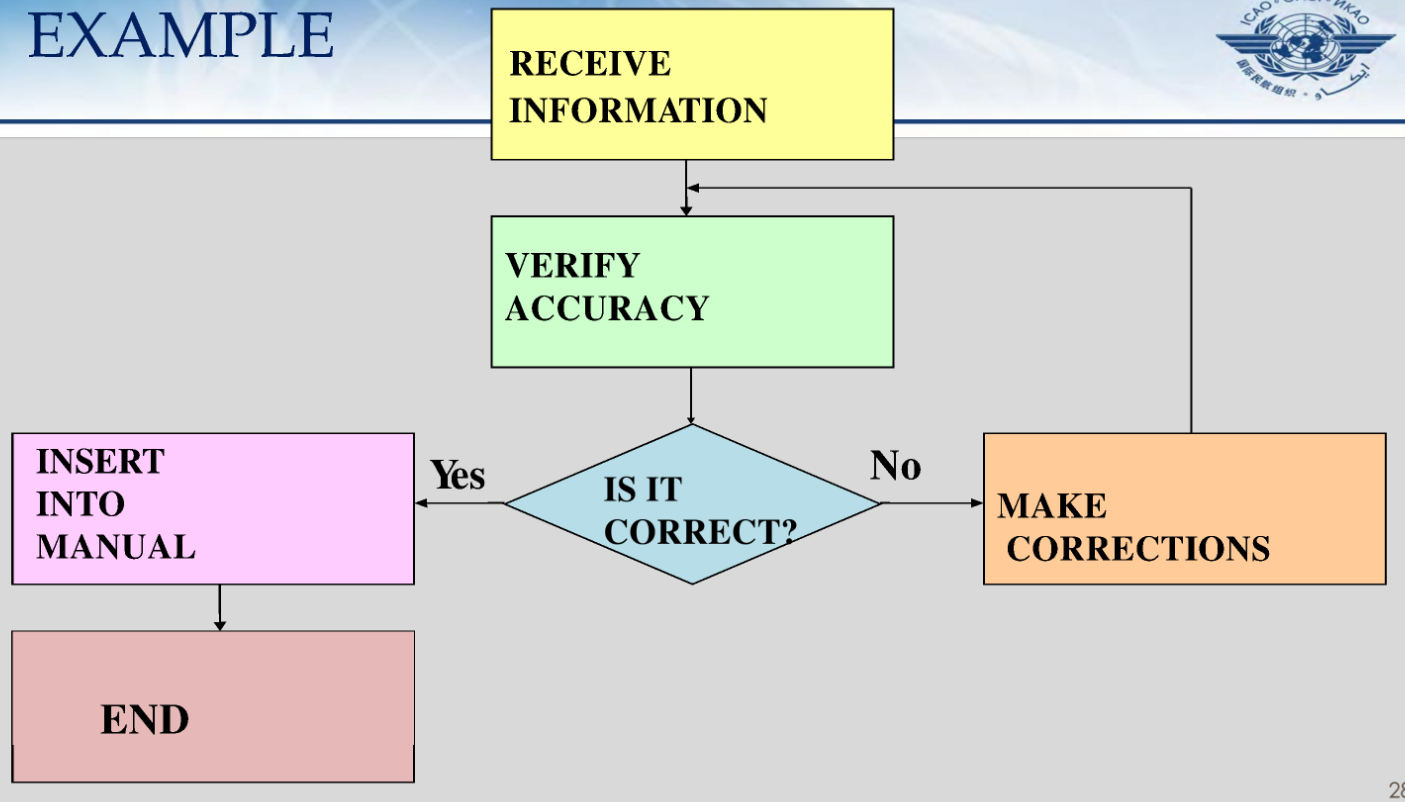
There is one route in and two possible routes out for the decision boxes

(e.g. yes/no or pass/fail)



27

EXAMPLE


RECEIVE INFORMATION
VERIFY ACCURACY
IS IT CORRECT?
Yes
No
INSERT INTO MANUAL
MAKE CORRECTIONS
END

28

IMPROVEMENT PHASE:
ACTIVITIES

29

AUDIT OBJECTIVES

(1) To ensure that procedures are being followed ie. We are doing what we say we do

(2)To determine the effectiveness of the systems and procedures in meeting the quality objectives

(3)To afford an opportunity to improve the quality system

30

AUDITING STANDARDS

ISO 10011 Guidelines for auditing quality systems

Part 1 : Auditing

Part 2 : Qualification criteria for quality systems auditors

Part 3 : Management of audit programmes

31

AUDIT

WHAT DOES THE ABOVE STANDARD SAY ABOUT QUALITY SYSTEMS AUDITING?

- Verify compliance, effectiveness
- Planned audit programme
- Independent auditors
- Documented procedure
- Timely corrective action
- Follow-up activities

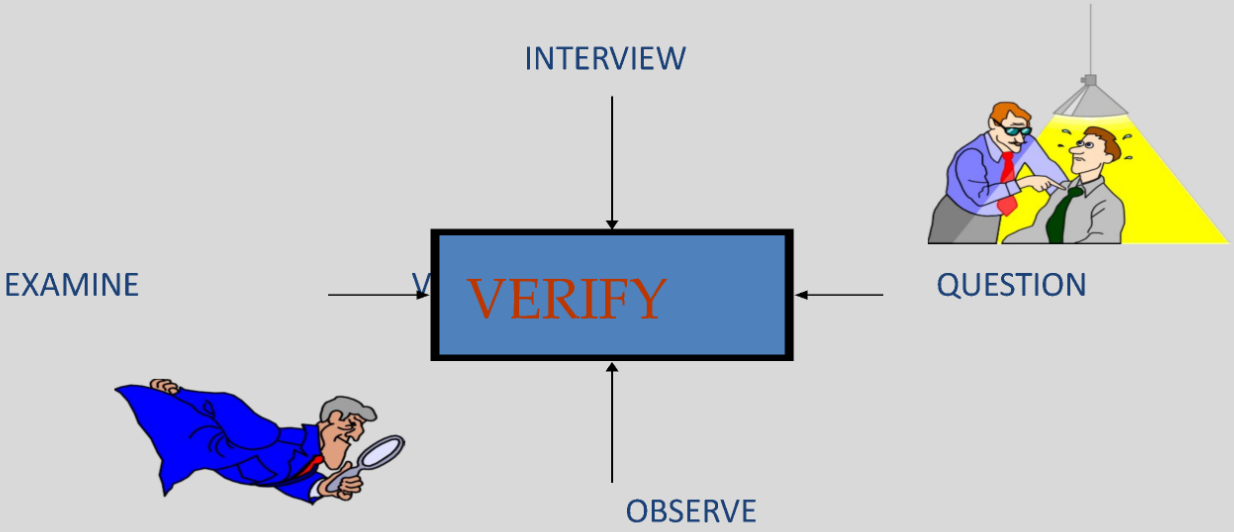
32

AUDIT PROGRAMME

- Audits planned in advance
- Audits are not random spot checks
- Scheduled usually by department, function, or process
- Consider the status and importance of process, and previous results

33

AUDIT TECHNIQUES



34

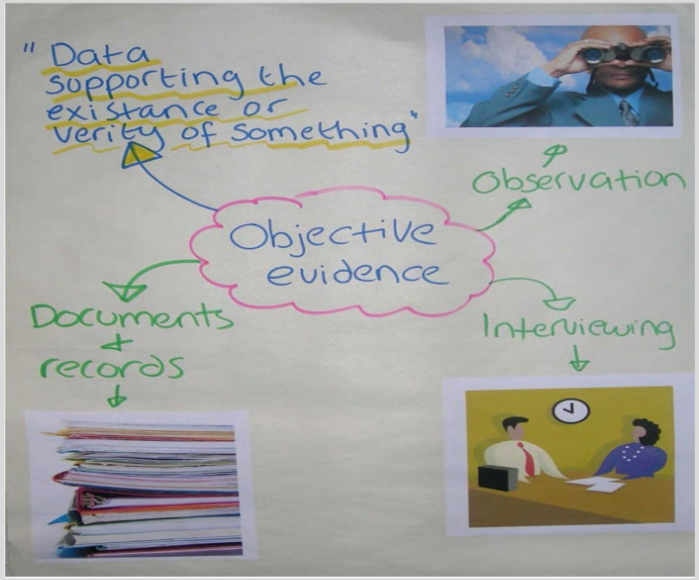
FOLLOW-UP

- Auditee responsible for corrective preventive actions
- Auditor follows-up action to ensure it is taken and effective
- Audit actions are closed - *records*

36

SUMMARY OF AUDIT PROCESS

- **PLANNING**
  Schedule, Preparation, Checklist
- **AUDITING**
  Opening Meeting, Audit, Closing Meeting
- **COMPLETION**
  Report, Corrective action, Follow-up



BENEFITS OF AUDITING

- Verifies that procedures are followed
- Reviews effectiveness of system
- Helps to identify problem areas
- Assists transfer of best practice
- Effective mechanism for continuous improvement

38

PREPARING FOR CERTIFICATION

ISO 9001- Steps in Implementation

- Management decision/commitment
- Decide scope of system
- Review current situation - report gaps
- Formulate action plan
- Document & implement processes
- Formal assessment

39

KEY QUESTIONS

Before inviting an external assessment:

check the following:

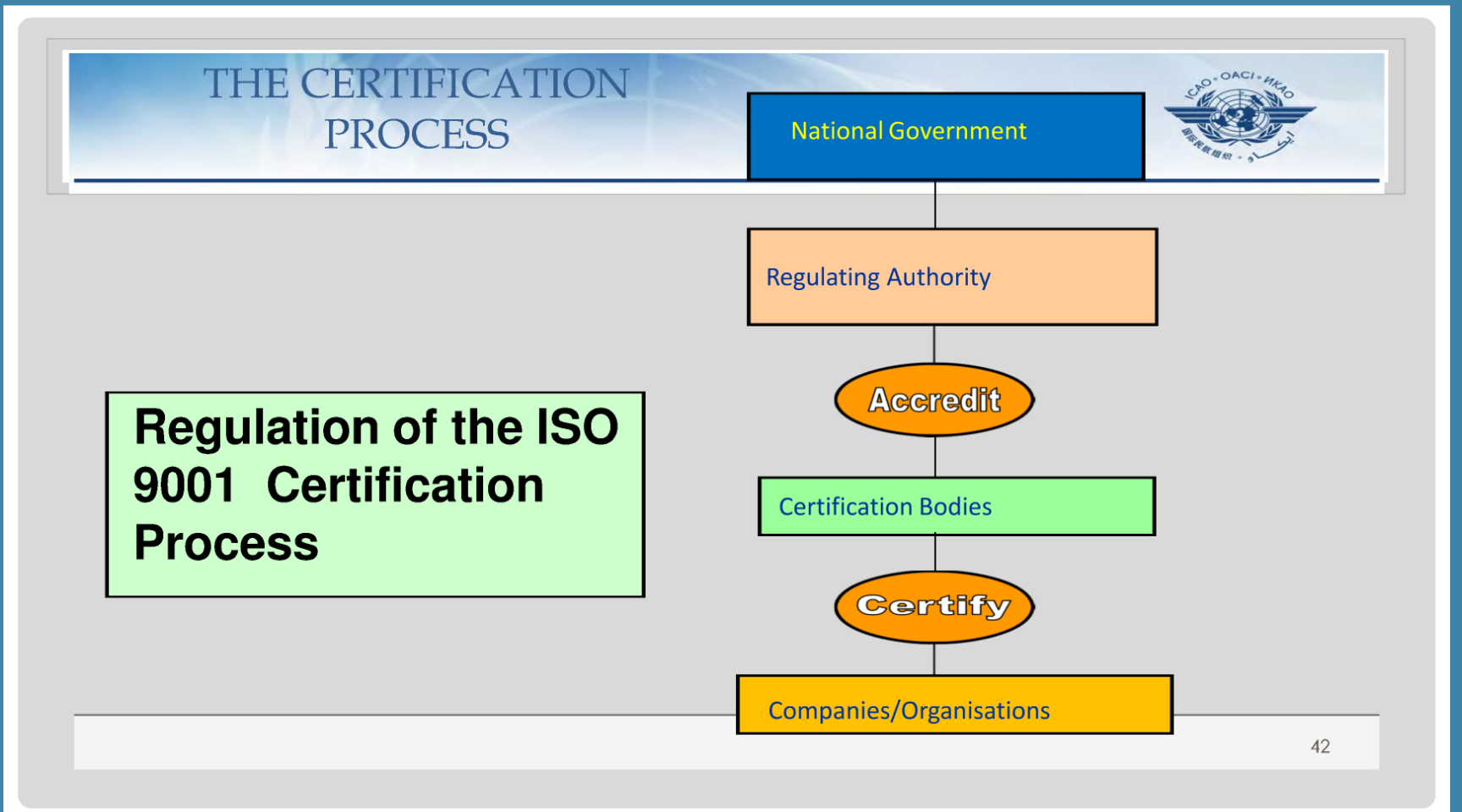
- Are the mandatory documents in place - quality manual and procedures?
- Are key processes identified and controlled?
- Have internal audits and management reviews been conducted?
- Are results from these satisfactory?

40

FINAL PREPARATION

- Consider a pre-assessment
  - internal
  - independent consultant
  - your assessment body
- Inform all of your staff
  - explain the process
  - clarify their responsibilities
  - seek their feedback regarding any concerns

41


THE CERTIFICATION PROCESS
National Government
Regulating Authority
Accredit
Certification Bodies
Certify
Companies/Organisations
Regulation of the ISO 9001 Certification Process
42

QUALITY MANAGEMENT PRINCIPLES

- Customer focused organization
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Factual approach to decision making
- Mutually beneficial supplier relationships
- Continual improvement

43

KEY PRINCIPLES OF ISO 9000

In summary:

1 GET ORGANISED
- define roles, responsibilities, interfaces

2 PROVIDE RESOURCES
- human resources, training, facilities

3 DOCUMENT MANAGEMENT SYSTEMS
- establish procedures, control documents

44

KEY PRINCIPLES OF ISO 9000

4 CONTROL PROCESSES
- plan processes, control operations

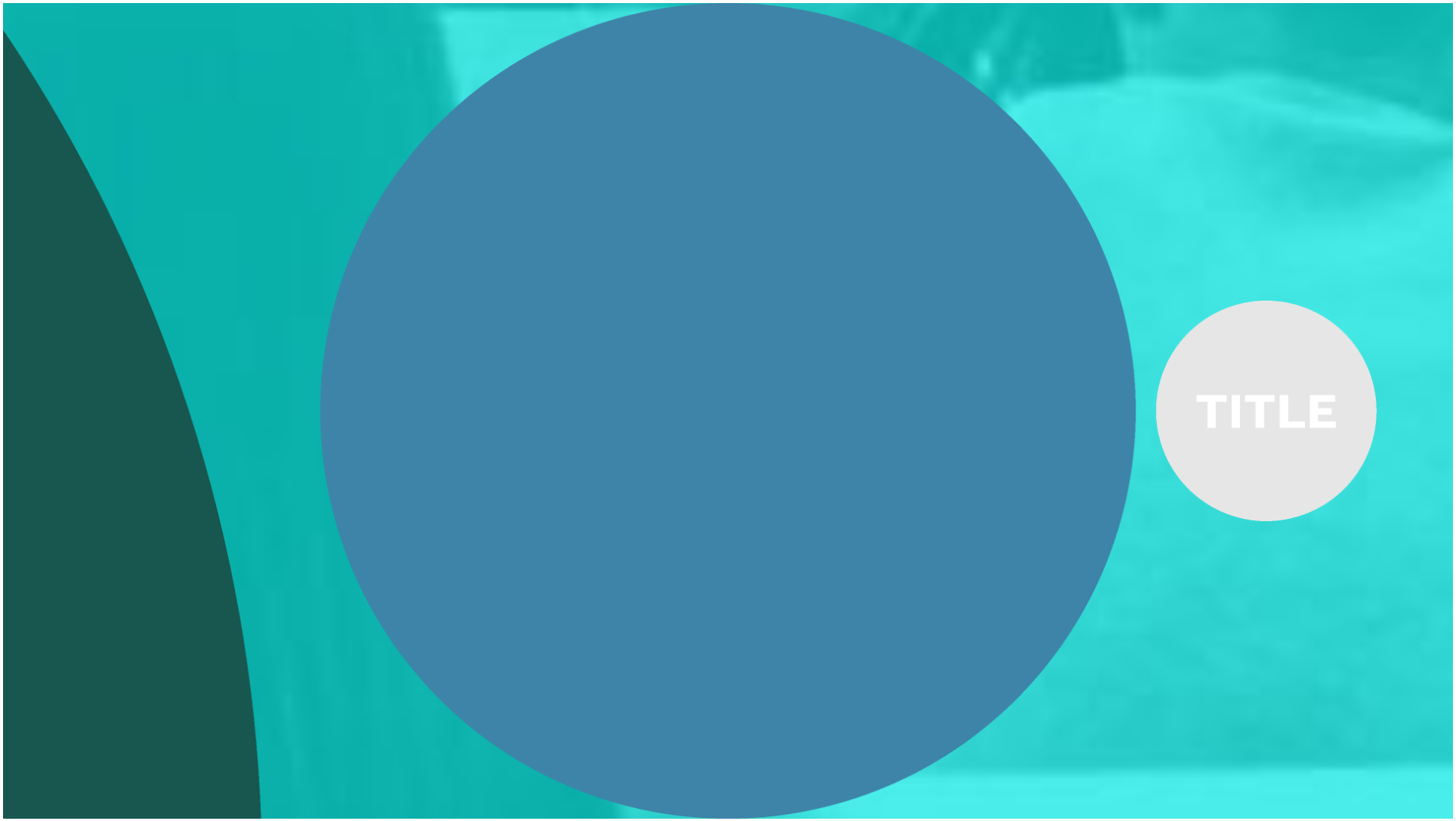
5 KEEP RECORDS OF ACTIVITIES
- evidence of effective operation

6 CARRY OUT REGULAR CHECKS
- inspections, tests, surveys, audits

7 IMPROVE THE SYSTEMS
- pro-active continual improvement process

45


The Elements
of Safety
Building
a
QMS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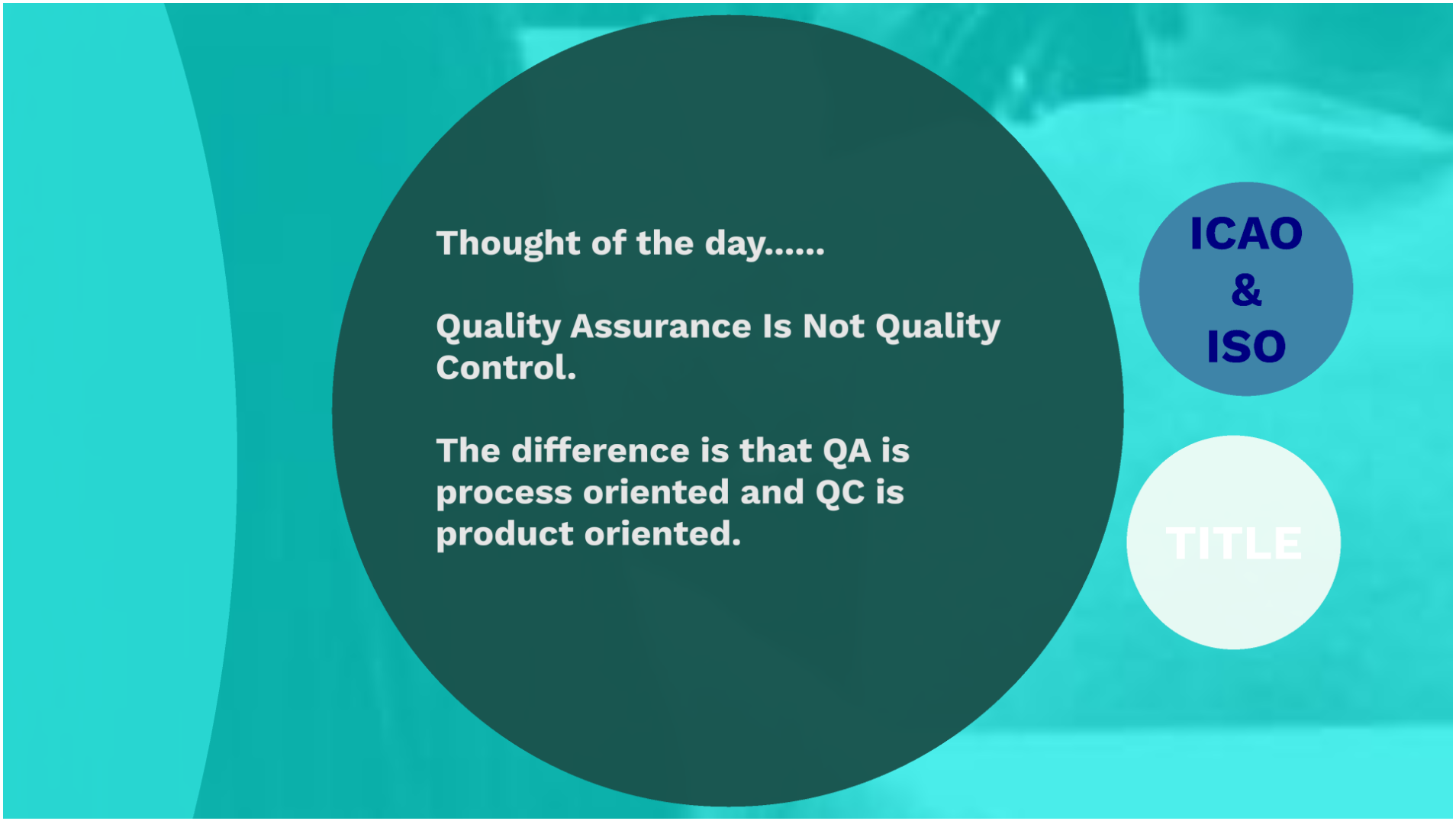
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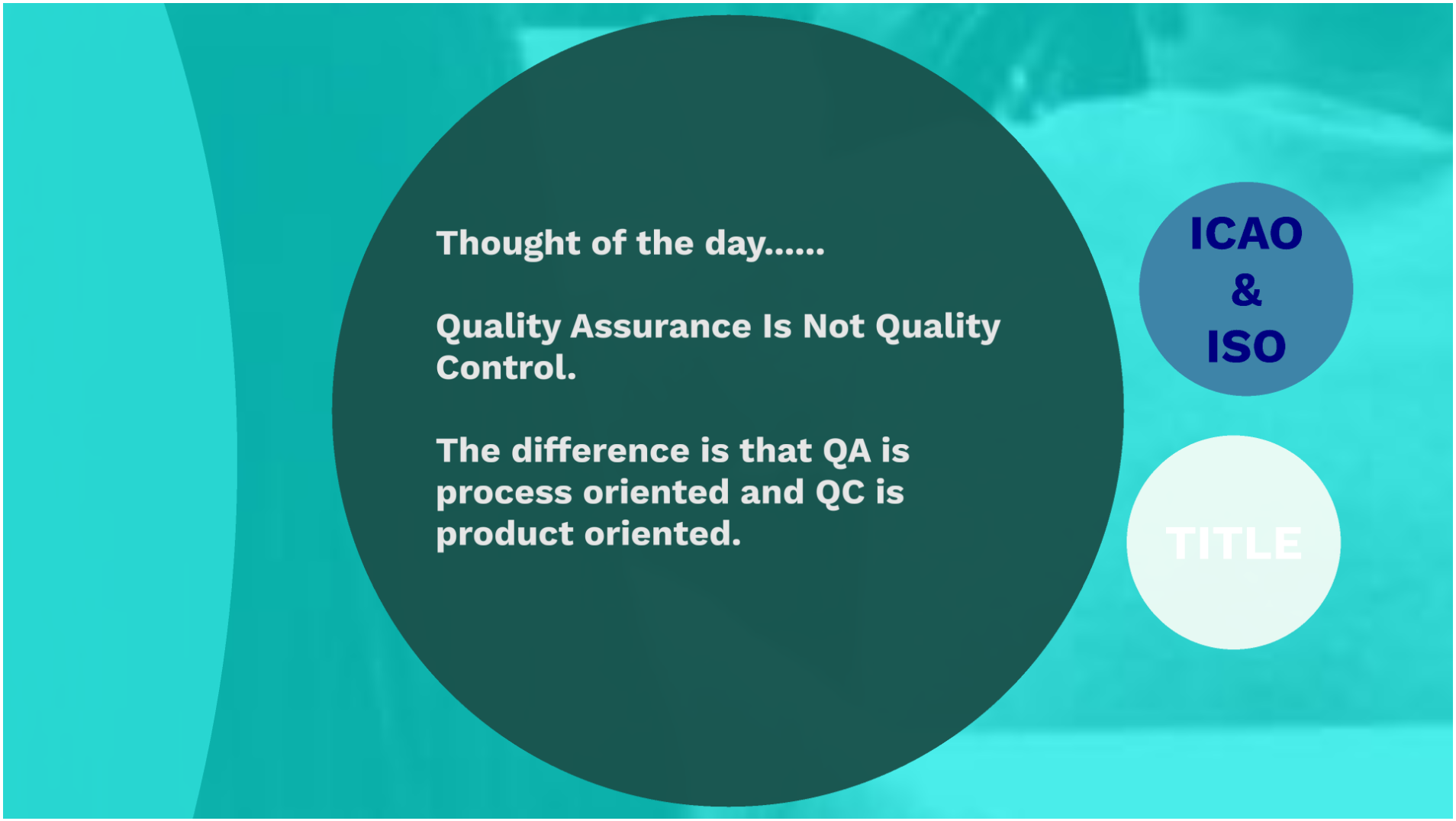
ICAO & ISO
TITLE

EXTRA QA Material

EXTRA QA Material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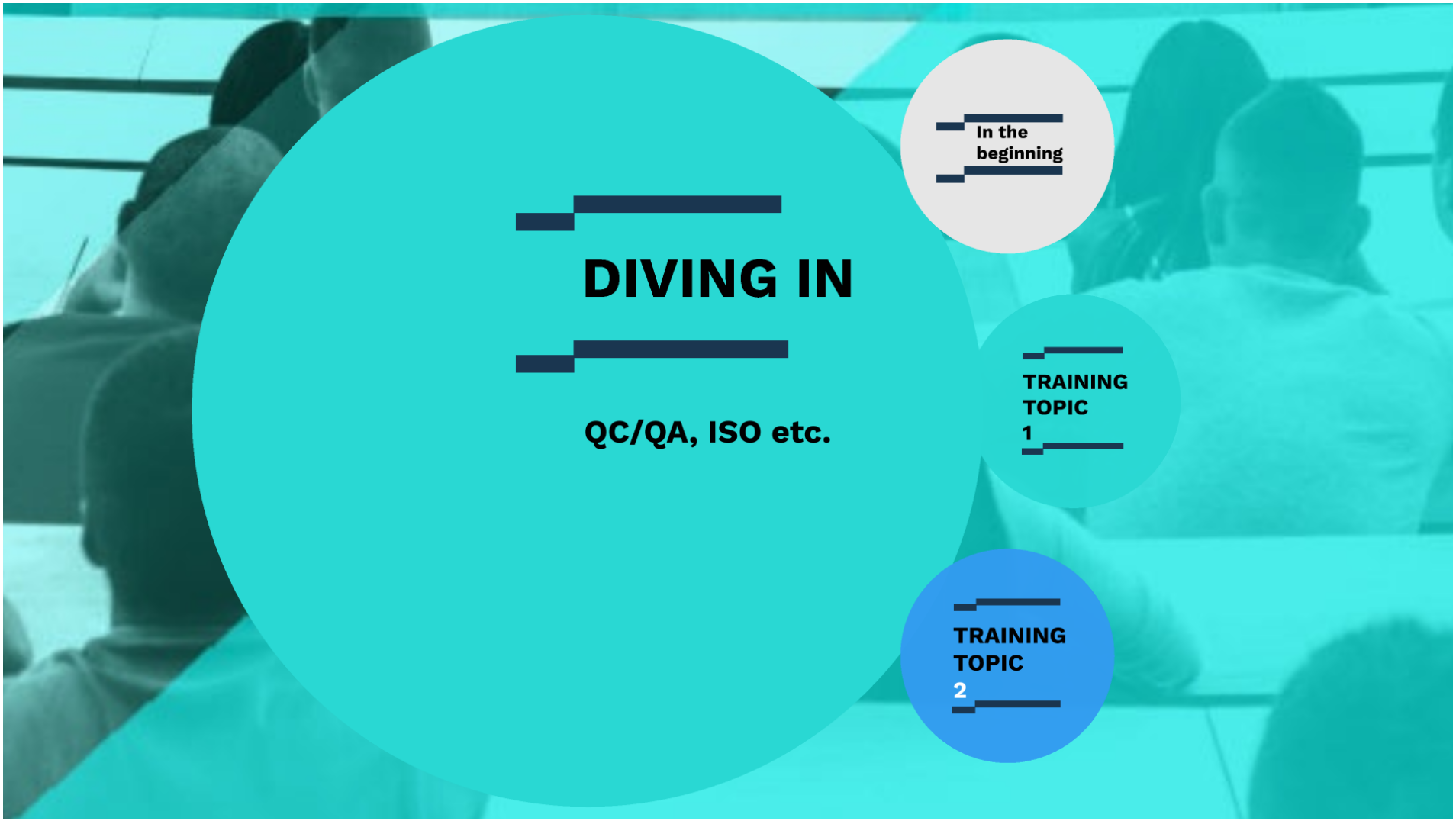
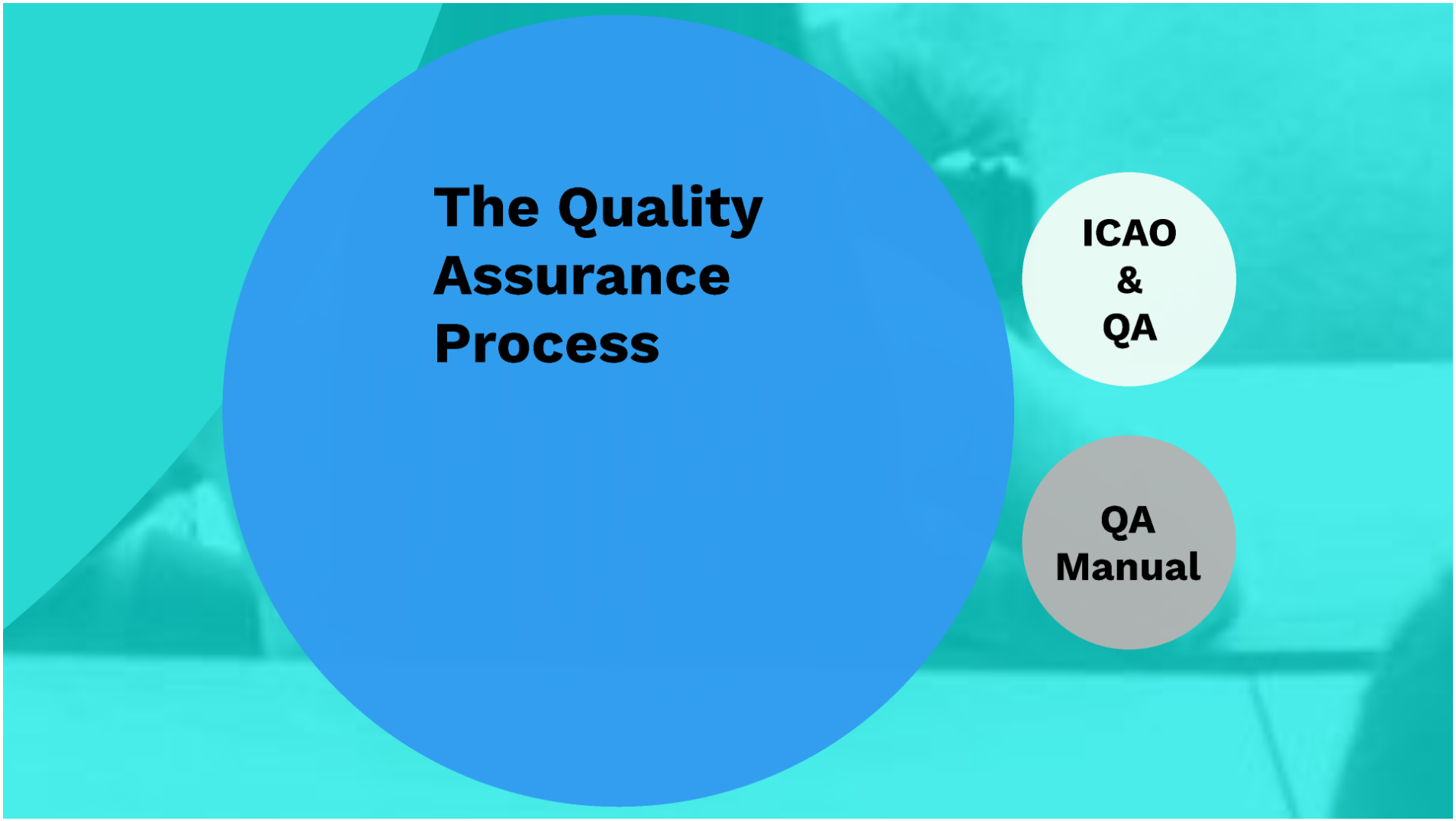
In The beginning -
The Start
QA VERSUS QC


In the beginning
DIVING IN
QC/QA, ISO etc.
TRAINING TOPIC 1
TRAINING TOPIC 2


The Quality Assurance Process
ICAO & QA
QA Manual

5.3.63 The safety assurance process complements that of quality assurance, with each having requirements for analysis, documentation, auditing and management reviews to assure that certain performance criteria are met.

While quality assurance typically focuses on the organization's compliance with regulatory requirements, safety assurance specifically monitors the effectiveness of safety risk controls.

5.3.64 The complementary relationship between safety assurance and quality assurance allows for the integration of certain supporting processes.

Such integration can serve to achieve synergies to assure that the service provider's safety, quality and commercial objectives are met.

Audits focus on the integrity of the organization's SMS and its supporting systems. Audits provide an assessment of safety risk controls and related quality assurance processes.

Audits may be conducted by entities that are external to the service provider or through an internal audit process having the necessary policies and procedures to ensure its independence and objectivity.

Audits are intended to provide assurance of the safety management functions, including staffing, compliance with approved regulations, levels of competency and training.

SMS and QMS integration

5.4.2.2 Aviation service providers typically implement enterprise-wide management systems. Organizational safety performance is dependent on the effective integration of these systems to support the delivery of products and services.

In the context of SMS, the most significant aspect of integration is with the service provider's quality management system (QMS).

QMS is generally defined as the organizational structure and associated accountabilities, resources, processes and procedures necessary to establish and promote a system of continuous quality assurance and improvement while delivering a product or service.

QMS is an existing aviation regulatory requirement for most service providers including production approval (Annex 8), maintenance organizations (Annex 6, Part I) and meteorological and aeronautical data service providers (Annexes 3 and 15, respectively).

The QMS also has an independent assurance function that utilizes a feedback loop to assure delivery of products and services that are "fit for purpose" and free of defects or errors.

The quality assurance function identifies ineffective processes and procedures that must be redesigned for efficiency and effectiveness.

Both quality and safety practitioners are trained on various analysis methods including root-cause analysis and statistical trending analysis.

5.4.2.7 Given the complementary aspects of SMS and QMS, it is possible to establish a synergistic relationship between both systems that can be summarized as follows:

a) an SMS is supported by QMS processes such as auditing, inspection, investigation, root cause analysis, process design, statistical analysis and preventive measures;

b) a QMS may anticipate safety issues that exist despite the organization's compliance with standards and specifications; and

c) quality principles, policies and practices are linked to the objectives of safety management.

Table 5-1. Summary comparison of QMS and SMS

QMS	*SMS*
Quality	Safety
Quality assurance	Safety assurance
Quality control	Hazard identification and risk control
Quality culture	Safety culture
Compliance with requirements	Acceptable level of safety performance
Prescriptive	Performance-based
Standards and specifications	Organizational and human factors
Reactive > Proactive	Proactive > Predictive

ANNEX 1

2.1 The training organization shall provide a training and procedures manual for the use and guidance of personnel concerned.

This manual may be issued in separate parts and shall contain at least the following information:

a) a general description of the scope of training authorized under the organization's terms of approval;
b) the content of the training programmes offered including the courseware and equipment to be used;
c) a description of the organization's quality assurance system in accordance with 4;
d) a description of the organization's facilities;

4. Quality assurance system

The training organization shall establish a quality assurance system, acceptable to the Licensing Authority granting the approval, which ensures that training and instructional practices comply with all relevant requirements.

ANNEX 3

Quality assurance. Part of quality management focused on providing confidence that quality requirements will be fulfilled
(ISO 9000*).

Quality control. Part of quality management focused on fulfilling quality requirements (ISO 9000*).

Quality management. Coordinated activities to direct and control an organization with regard to quality (ISO 9000*).

2.2.3 Recommendation.— The quality system established in accordance with 2.2.2 should be in conformity with the ICAO (ISO) 9000 series of quality assurance standards and should be certified by an approved organization.

Note.— The ICAO (ISO) 9000 series of quality assurance standards provide a basic framework for the development of a quality assurance programme.

The details of a successful programme are to be formulated by each State and in most cases are unique to the State organization. Guidance on the establishment and implementation of a quality system is given in the Manual on the Quality Management System for the Provision of Meteorological Service to International Air Navigation (Doc 9873).

ANNEX 4

Note 2.— Error producing faults in the entire process may be mitigated by additional data quality assurance techniques as may be required.

These could include application tests for critical data (for example, by flight check); the use of security, logic, semantic, comparison, and redundancy checks; digital error detection; and the qualification of human resources and process tools such as hardware and software.

ANNEX 6

Maintenance organization's procedures manual.

**A document endorsed by the head of the maintenance organization which details the maintenance organization's structure and management responsibilities, scope of work, description of facilities,
maintenance procedures and quality assurance or inspection systems.**

8.7.4 Maintenance procedures and quality assurance system

8.7.4.1 The maintenance organization shall establish procedures, acceptable to the State granting the approval, which ensure good maintenance practices and compliance with all relevant requirements of this chapter.

8.7.4.2 The maintenance organization shall ensure compliance with 8.7.4.1 by either establishing an independent quality assurance system to monitor compliance with and adequacy of the procedures, or by providing a system of inspection to ensure that all maintenance is properly performed.

ANNEX 15

Quality. Degree to which a set of inherent characteristics fulfils requirements (ISO 9000*).

Note 1.— The term “quality” can be used with adjectives such as poor, good or excellent.

Quality assurance. Part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000*).

Quality control. Part of quality management focused on fulfilling quality requirements (ISO 9000*).

Quality management. Coordinated activities to direct and control an organization with regard to quality (ISO 9000*).

3.7.3 Recommendation.— The quality management system established in accordance with 3.7.1 should follow the International Organization for Standardization (ISO) 9000 series of quality assurance standards, and be certified by an approved organization.

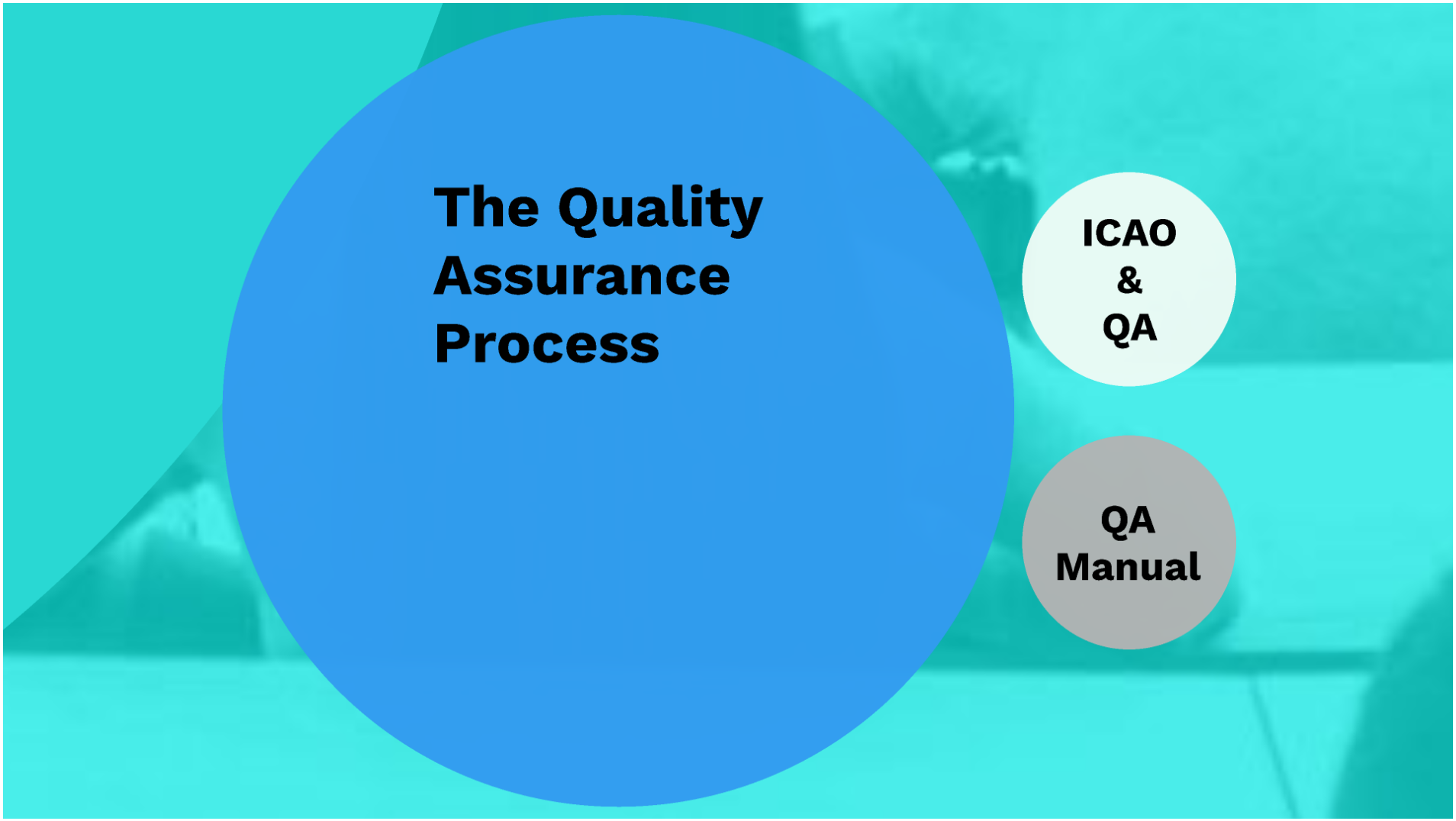
3.7.4 Within the context of the established quality management system, the competencies and the associated knowledge, skills and abilities required for each function shall be identified, and personnel assigned to perform those functions shall be appropriately trained.

Processes shall be in place to ensure that personnel possess the competencies required to perform specific assigned functions.

Appropriate records shall be maintained so that the qualifications of personnel can be confirmed.

Initial and periodic assessments shall be established that require personnel to demonstrate the required competencies.

Periodic assessments of personnel shall be used as a means to detect and correct shortfalls.


The Quality Assurance Process
ICAO & QA
QA Manual


Develop a QA Process
HOW?

CORPORATE QUALITY MANUAL (CQM)

CORPORATE SAFETY & SECURITY DEPARTMENT Rev. 00 (10 Aug 2015)

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TABLE OF CONTENT

8 QUALITY ASSURANCE

8.1 INTRODUCTION

The objective of quality assurance is to verify that all planned and systematic activities within the quality system are demonstrated, in order to provide adequate confidence that they fulfil the intended requirements. Such systems and activities include (but are not limited to):

i. Terms of Reference for embedded departmental Quality Officers
ii. Independent Quality systems
iii. Audit systems, programmes and planning
iv. Audit processes
v. Audit procedures and instructions
vi. Audit training
vii. Manuals, documents and data control
viii. Records and record keeping
ix. Contracted or sub-contracted services
x. Alliance and code-share operations
xi. IOSA
xii. Consolidated port audit programme
xiii. Safety and security database (AQD)
xiv. Feedback systems

An effective audit program includes:

i. Audit initiation, including scope and objectives;
ii. Planning and preparation, including audit plan and checklist development;
iii. Observation and gathering of evidence;
iv. Analysis, findings, actions;
v. Reporting and audit summary;
vi. Follow-up and close out.

8.2 PURPOSE

(The Operator) shall develop, implement and maintain a quality assurance program that provides for the auditing and evaluation of the management system, and of operations and maintenance functions, to ensure the Company is:

i. Complying with applicable internal regulations and standards
ii. Satisfying stated operational needs
iii. Identifying areas requiring improvement
iv. Identifying hazards to operations.

8.3 ANNUAL AUDIT PLAN (SCHEDULE)

Each department shall develop and maintain an annual audit plan (schedule) detailing the audit activities from 1 January to 31 December.

The audit plan shall be prepared in Q4 of each year for the following year.

The audit planning process shall ensure that sufficient resources are made available to ensure audits are:

i. Scheduled at intervals to meet regulatory and management system requirements;
ii. Completed within the specified time period

Corrective actions shall be raised for all deficiencies noted during the audit process and shall be appropriate to the effects and root causes of non-conformity and shall be designed to prevent any recurrence.

When determining the level of action to be taken, safety, quality and security shall be primary considerations.

Audit follow-up activities shall include the recording and verification of corrective action implementation within a reasonable timeframe.

A record shall be maintained of all regulatory non-conformances.

Each department shall implement, develop and maintain a process for addressing findings that result from audits conducted under the quality assurance program, which ensures:

i. Identification of root cause(s);
ii. Development of corrective action as appropriate to address findings;
iii. Implementation of corrective action in appropriate operational area(s);
iv. Evaluation of corrective action to determine effectiveness.

The Quality Representative or person assigned with responsibility to address the corrective action shall investigate to ascertain the root cause of the finding.

From this information, such responsible person will determine what actions are needed to eliminate the root cause of the finding.