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Airworthiness Inspector’s Classroom and On-the-Job Training together with review of Handbooks and Procedures

Phnom Penh, Cambodia

10-26 June 2019

Omer Pita and Salvador Alepuz
Airworthiness Experts

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ICAO and EASA Regulatory Framework for Aircraft Maintenance Programs

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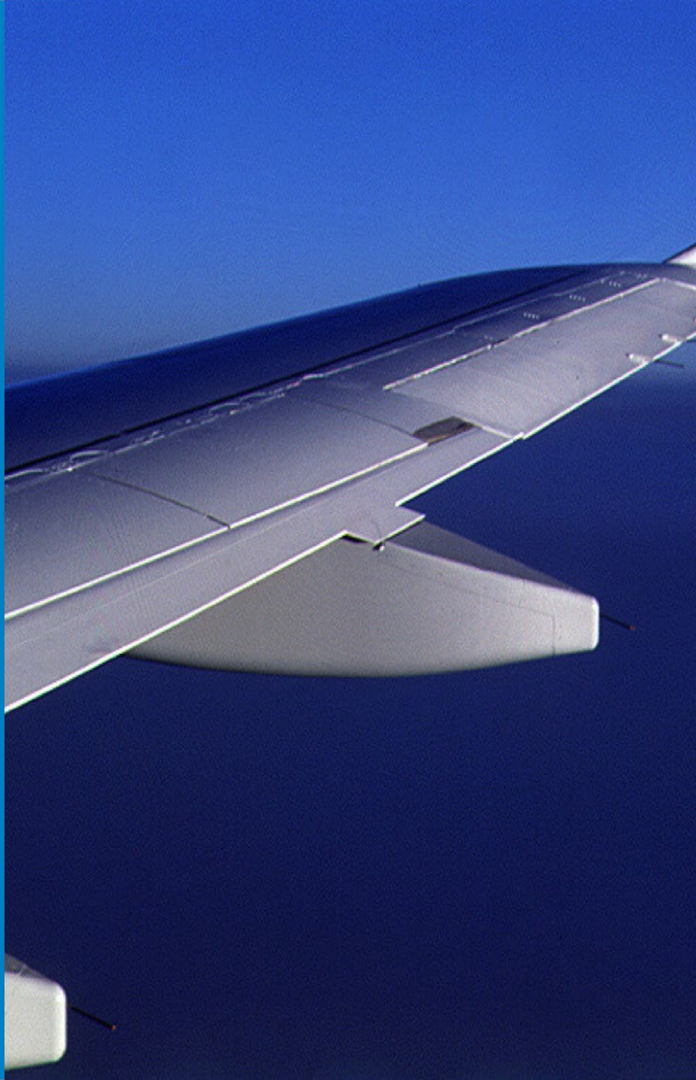
International Regulatory Bodies and Their Regulations



International Civil Aviation Organization ICAO

- The International Civil Aviation Organization (ICAO) is a specialized agency of the United Nations.
- It defines international civil aviation standards and recommended practices
- Its headquarters are located in Montreal, Canada.
- It has been established by the Convention on International Civil Aviation, also known as the Chicago Convention, in Chicago, Illinois, on 7 December 1944.
- ICAO begun its operations on 4 April 1947, and in October 1947, ICAO became an agency of the United Nations linked to the United Nations Economic and Social Council (ECOSOC)

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End of presentation

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Introduction to Aircraft Maintenance Programs

Omer Pita and Salvador Alepuz
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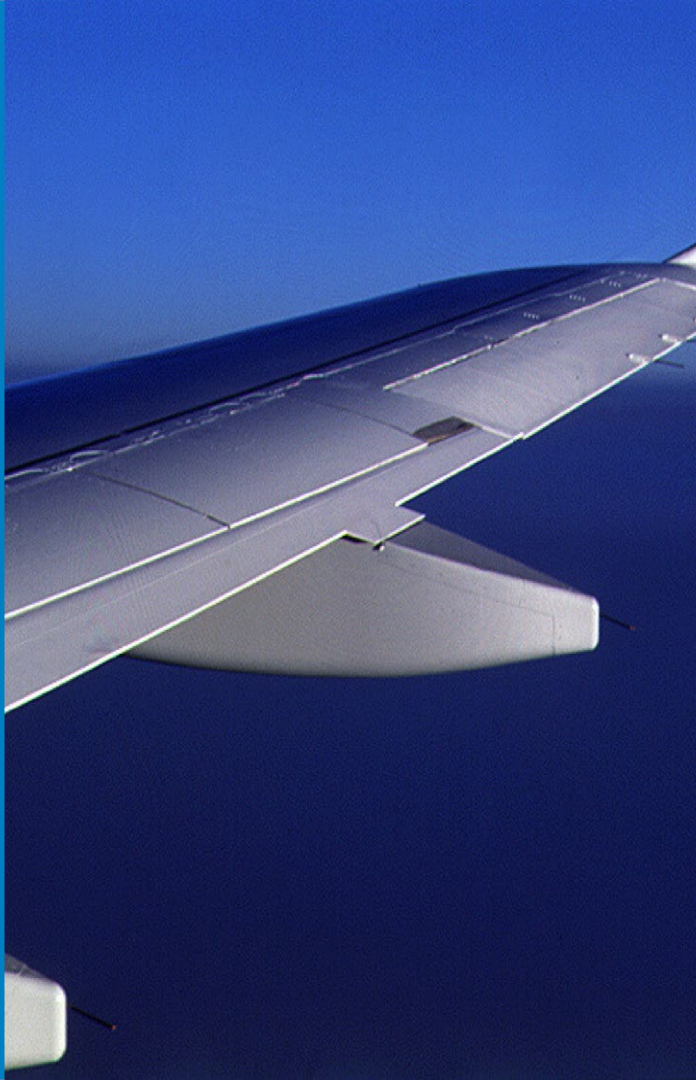
Course introduction



Participants introduction

- Name
- Profession
- Former experience
- Organizational unit
- Current job
- Experience in Aviation
- Your expectations of this training course

Ground Rules of the Course

- Course is divided in 1-1.5 hours sessions with 10-15 min brakes in between and one 45 min pause for lunch.
- Please be on time for each session
- Please switch off your mobile/GSM/Handy
- Try to wait for the breaks if you need to use your mobile phone
- Please do not use your laptop or read emails during the course sessions
- Feel free to rise questions/comments anytime during the course

Course Content

→ **Session 1:**

- →Introduction
- →Regulatory Requirements for a Maintenance Programme (ICAO and EU regulations with respect to continuing airworthiness and AMPs);
- →TC (Type Cert.) Holder processes, MRB process relating to developing A/C maintenance programmes (AMP);
- →MRB report, Maintenance Planning Document, Supplemental Inspection Documents;

→ **Session 2:**

- →Maintenance steering group (MSG) history, MSG 1/2/3 analysis, design requirements relating to scheduled maintenance, what is MSG? How does MSG3 compare with MSG2/MSG1;
- →Systems / Powerplant Programme;
- →Structures Programme Development/ Airworthiness Limitation Items;
- →Zonal Programme Development;
- →LHIRF.

Course Content

- **Session 3:**
  - Airworthiness Requirements (CMR, ALI, ADs...), In service experience (SIL, SB...)
  - Ageing structures /zonal inspections (CPCP), Fuel system safety (CDCCL),
  - Electrical wire interconn. systems (EWIS)
  - Differences between Generic, Baseline, Low Utilisation Programmes and Customised AMP;
  - Significance of the interactions between design requirements, maintenance programme development, maintenance standards and inspection standards;

- **Session 4**
  - Checking the contents of AMPs for compliance with Authority requirements (EASA Part M);
  - Approval of AMPs including assessing the process for In House approval for Operators;
  - Processes associated with operator, management of maintenance programmes including escalation and optimisation, engine and component off-wing programmes, storage maintenance, alignment / bridging checks;

Course Content

- **Session 5**
  - Reliability Programmes and Reports;
  - Regulatory requirements
  - Purpose of reliability program
  - Structure of reliability program
  - Reliability program process flow,
  - Reliability performance Indicators
  - Calculation of Alert levels
  - Analysis and Reporting

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Aircraft Maintenance General

What makes the aviation special?

Aircraft as a technical device

- Average narrow body transport category aircraft is:
  - In essence a huge pressurized tube with average mass of 90 tons, which is moving through open space at the altitudes up to 15 000 meters, with approximate speed of 900 km/hr.
  - It is the only transport vehicle (aside submarines) that travels in 3D space.
  - Flying is being achieved by the aircraft being supported by the moving air which creates adequate aerodynamic force to hold the whole weight of the aircraft in the air. Therefore, the aircraft can not stop in the air.
  - To be able to produce required thrust throughout the flight, aircraft has to have tens of tons of highly combustible fuel on board.
  - Operations are carried out in almost all visibility conditions, day and night.
  - Take-off and landing typically take place at speeds between 130-300 km/h and it is performed on the runways 2-3 km long and 30-70 meters wide.

Aviation is a „high risk” human activity

- Aviation is classified into high risk industries, in the same category as oil rigs and nuclear powerplants.
- Due to their nature, high risk industries are highly regulated and have to continuously carry on activities to keep the risks at the acceptable level:
- Main risk abatement methods:
  - Regulations
  - Utilisation of new technologies aimed at risk reduction
  - Procedures and standardization of the operations
  - <u>Maintenance</u>
  - Education of personnel

Technology and technical aspects

→ Taking into the account the specific conditions in which the aircraft operates, specific aircraft technologies had to be and are still being developed. Some of these technologies are unique to the aerospace industries.

→ To maintain adequate safety levels, safety relevant aircraft systems have to be designed to be failsafe. This is mostly achieved by introducing the redundancy into the system by installing parallel systems with same functionality that can be deployed in case the primary system fails.

Technology and technical aspects

- → There is the increasing number of the aircraft systems that are being introduced with the sole purpose of increasing the flight safety (ACAS, GPWS...)
- → Downside of this improvements is that modern aircraft today are very expensive machines
- → To be able to amortize such high aircraft prices, they are projected to have economic life of more than 20 years, or for narrow body, typical structure design life is between 50.000-80.000 flights.

Objectives of Aircraft Maintenance

Objectives of Aircraft Maintenance

- The complexity and longevity of current commercial aircraft, particularly in line with the imperative to assure adequate level of flight safety, determines the scope and objectives of aircraft maintenance.

Objectives of Aircraft Maintenance

→ In accordance with MSG 3 (Maintenance Steering Group) definition, aircraft scheduled maintenance is a set of activities that has following objectives:

a) To ensure realization of the inherent safety and reliability levels of the aircraft.

b) To restore safety and reliability to their inherent levels when deterioration has occurred.

c) To obtain the information necessary for design improvement of those items whose inherent reliability proves inadequate.

d) To accomplish these goals at a minimum total cost, including maintenance costs and the costs of resulting failures.

The Limitation of Aircraft Maintenance

- These objectives recognize that scheduled maintenance, as such, cannot correct deficiencies in the inherent safety and reliability levels of the aircraft.
- The scheduled maintenance can only prevent deterioration of such inherent levels.
- If the inherent levels are found to be unsatisfactory, design modification is necessary to obtain improvement.

Sources of Aircraft Deficiencies or Defects

- DESIGN
  - TOLERANCES TO LOOSE (specifications)
  - IMPROPERLY UNDERSTOOD ENVIRONMENT.
  - INADEQUATE TESTING, DESIGN NOT CONFIRMED.
  - COMPONENT RELIABILITY NOT UNDERSTOOD.
- MANUFACTURING
  - MATERIAL SUBSTITUTIONS.
  - IMPROPER PROCESSES (MFG. AND ASSEMBLY).
  - CONTAMINATION.
  - MACHINE OPERATIVES NOT PROPERLY TRAINED.
  - IMPROPER MATERIAL TREATMENT
- OPERATION
  - LOADS EXCEED PREDICTED ENVIRONMENT.
  - NEW ENVIRONMENT (also storage).
  - POOR ERGONOMICS (human engineering)

Effects of Maintenance on the Quality of Operation

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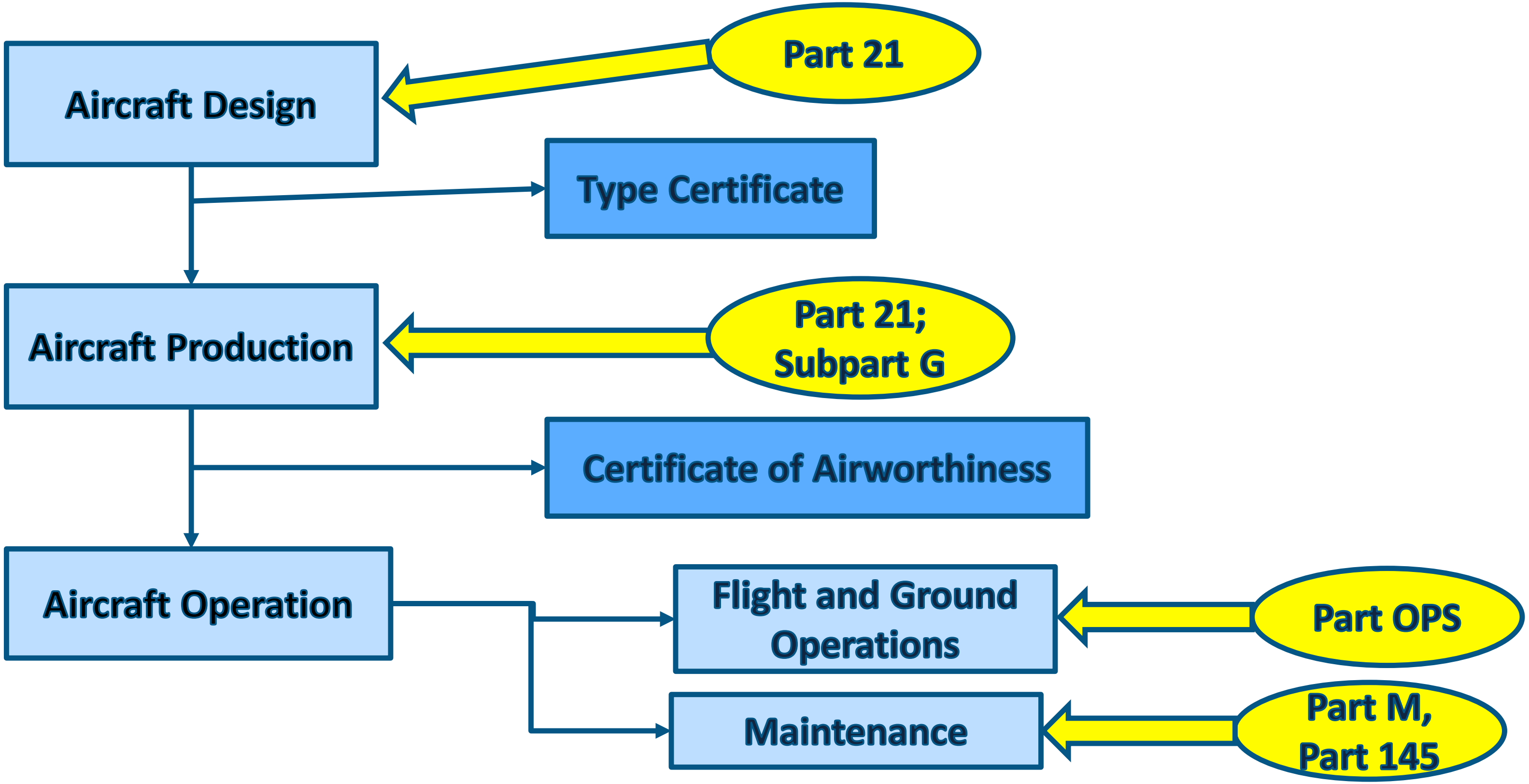
Technical Status of Aircraft – Share of Responsibilities

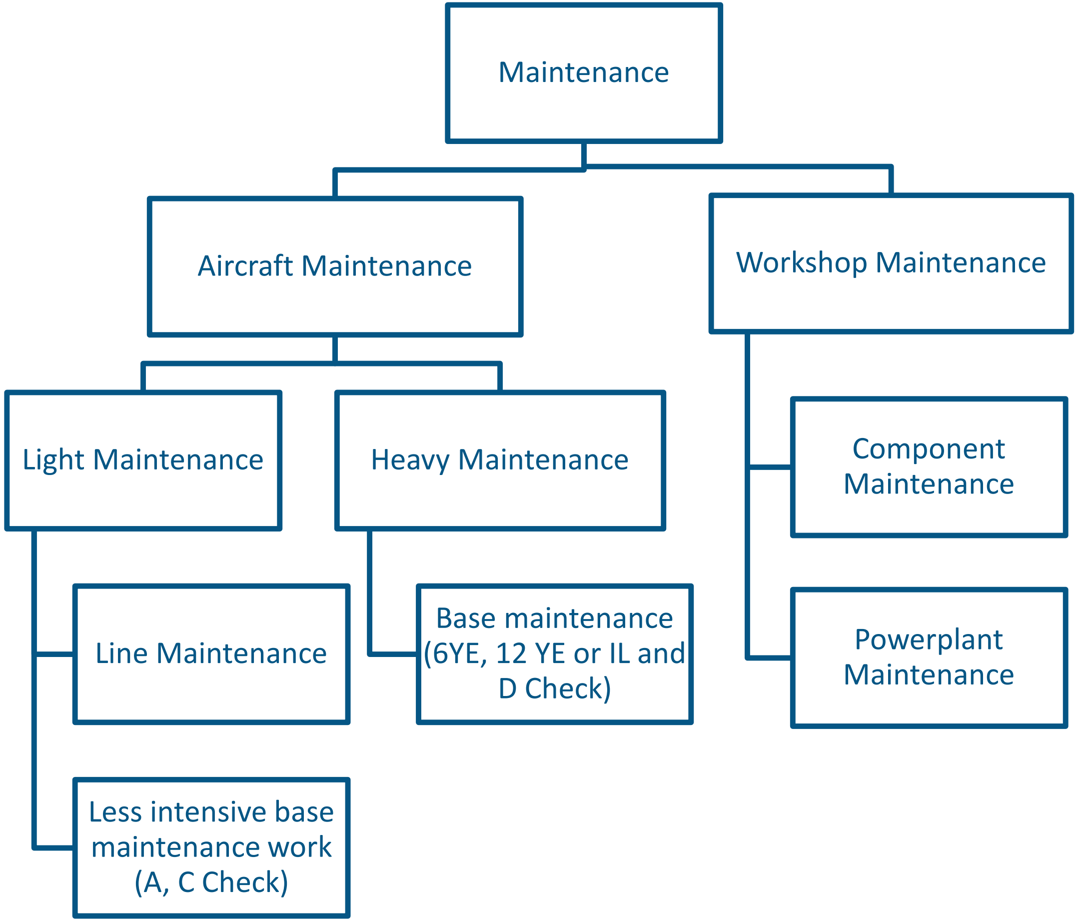


Classification of Maintenance

Classification of Maintenance

- There are several ways to divide Maintenance. From the point of view of the Maintenance Program, it can be divided in:
  - Scheduled maintenance – maintenance that is repetitively performed in intervals in accordance with defined Maintenance Program, generally speaking it is <u>preventive maintenance</u>
  - Unscheduled maintenance – maintenance that is carried out in order to restore designed condition of the aircraft after failure or damage occurred, frequently named <u>reactive maintenance</u>
  - Modifications – by definition are not considered to be maintenance, but are performed by AMOs

Classification of Maintenance Relative to the Maintenance Scope



Aircraft Maintenance

- It includes maintenance of the airframe and aircraft systems performed directly on the Aircraft:
  - Aircraft systems maintenance
  - Engine & APU "on wing" maintenance
  - Aircraft Structure maintenance & repair
  - Generally includes all maintenance activities that are defined in relevant AMM and SRM
- *Aircraft maintenance* is usually divided on Light Maintenance and Heavy Maintenance.
- Light Maintenance comprises of:
  - Line Maintenance and
  - Lower checks of Base Maintenance (A, C check)

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Line & Base Maintenance - *EASA definition*

- **Line maintenance** means any maintenance that is carried out before flight to ensure that the aircraft is fit for the intended flight. It may include:
  - trouble shooting;
  - defect rectification;
  - component replacement with use of external test equipment, if required. Component replacement may include components such as engines and propellers;
  - scheduled maintenance and/or checks including visual inspections that will detect obvious unsatisfactory conditions/discrepancies but do not require extensive in depth inspection. It may also include internal structure, systems and powerplant items which are visible through quick opening access panels/doors;

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Line & Base Maintenance cont'd

- minor repairs and modifications which do not require extensive disassembly and can be accomplished by simple means;
- for temporary or occasional cases (Airworthiness Directives, hereinafter AD; service bulletins, hereinafter SB) the quality manager may accept base maintenance tasks to be performed by a line maintenance organisation provided all requirements are fulfilled. The Member State will prescribe the conditions under which these tasks may be performed.

- **Base Maintenance** means any task falling outside the criteria that are given above for *Line Maintenance*.

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Workshop Maintenance

- *Workshop maintenance* is maintenance carried out in the workshops on aircraft engines or aircraft components that have been removed from the aircraft.
- As a rule, workshop maintenance is performed in accordance with Component Maintenance Manual (CMM), or Overhaul Manual (OHM)
- Workshops are specialized for a narrow scope of components within specific aircraft systems due to the technology and equipment that is being used to perform maintenance tasks

Aircraft Maintenance Program

Responsibility of the Operator to Develop the Maintenance Program

- Why is it operator's responsibility?
- Operation of the same type of the aircraft can be largely different between different operators:
  - Geographical region (tropic-polar; sea-land; high regions – low regions...)
  - Type of the operation (short haul - long halul; scheduled – charter...)
  - Utilisation (Low utilisation, High utilisation)
  - Operating and maintenance procedures and standards (flight planning, fuel policies, MEL application, preventive maintenance....)
- Therefore, to account for all specifics to its operation, each operator is required to develop its own maintenance program.
- MPD is being developed by the manufacturer as a baseline program recommendation, reflecting the average operation and specified (average) range of aircraft utilisation

Definition of AMP (EASA)

- AMC M.A.302 Aircraft Maintenance Programme (definition) „1. The term “maintenance programme” is intended to include scheduled maintenance tasks the associated procedures and standard maintenance practices.„

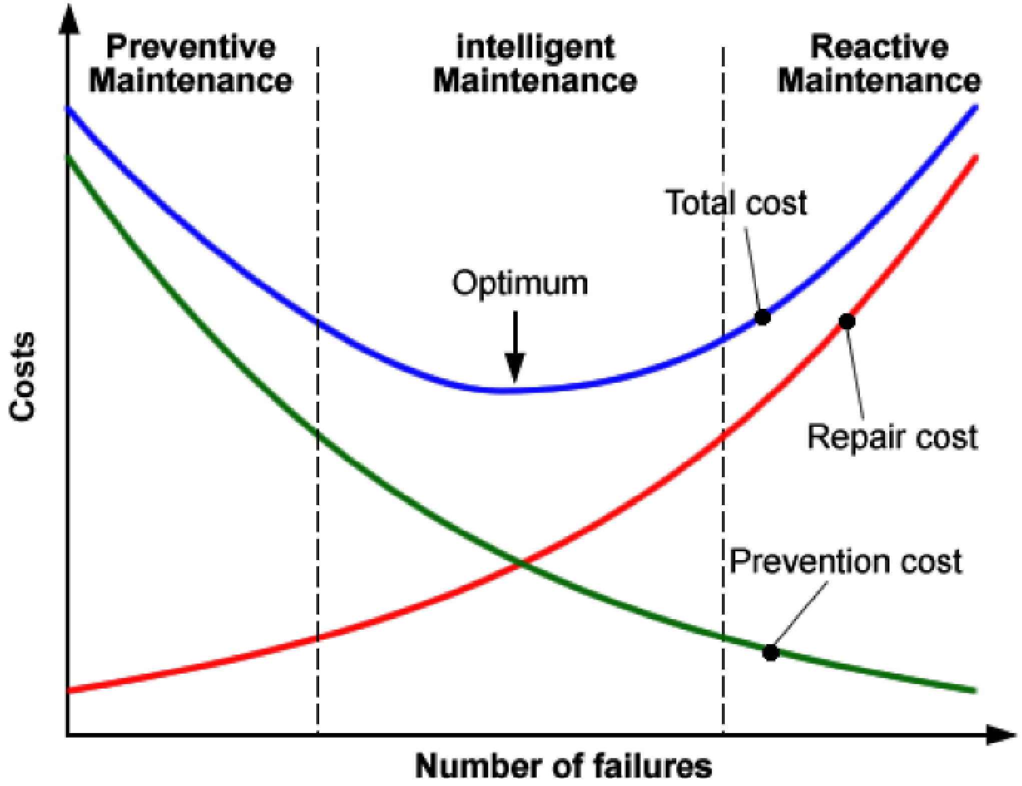
- As it is visible from the definition, focus is on scheduled (preventive) maintenance.

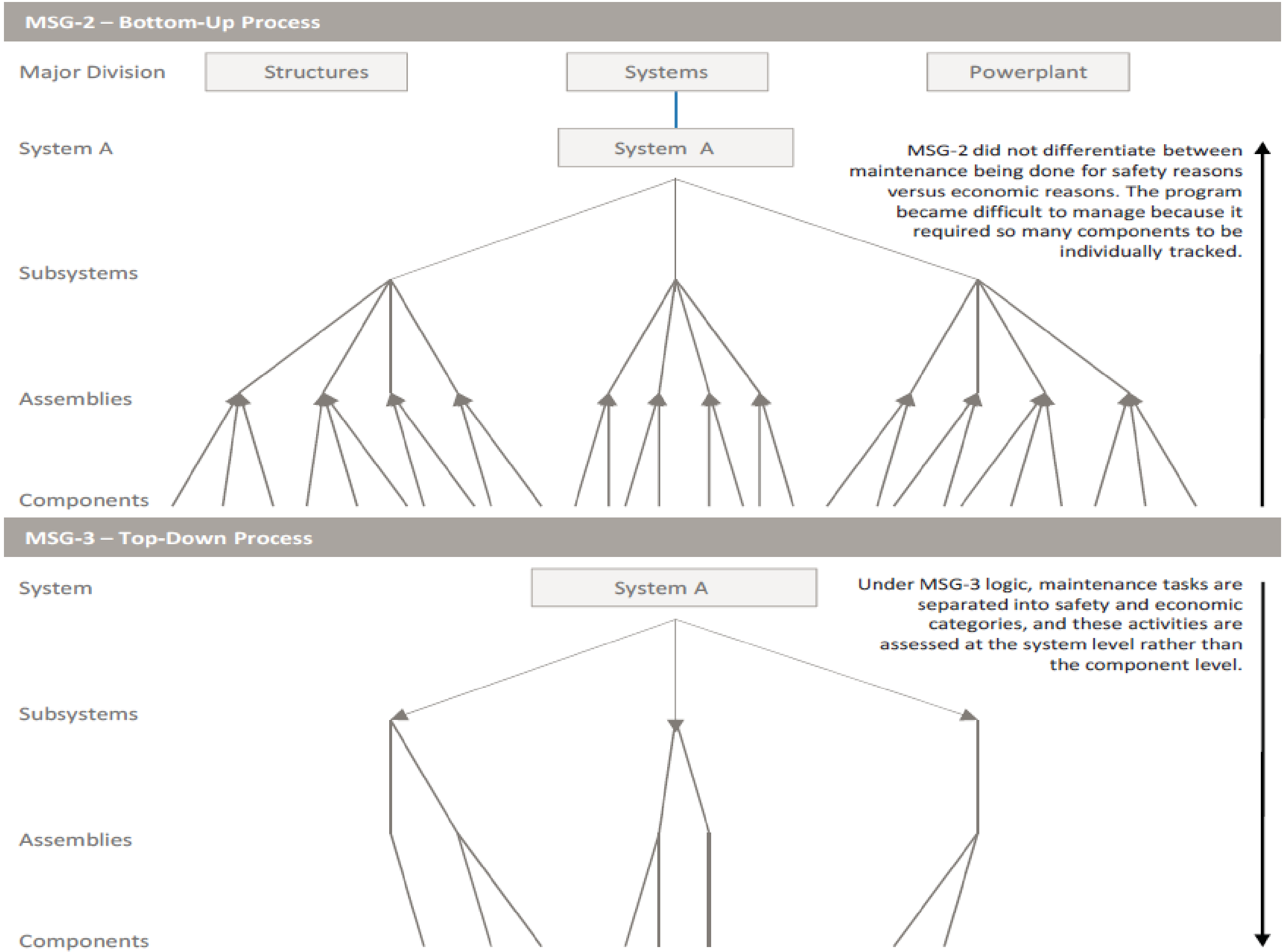
Basis for the Development of the Maintenance Program

- Modern Maintenance Programs are based on the approach developed by ATA - MSG (Air Transport Association - Maintenance Steering Group).

- Today, we have two versions of MSG documents that are in use by the industry: Maintenance Steering Group-2 (MSG-2), as older logic that is still in use with some older aircraft and Maintenance Steering Group-3 (MSG-3) being the current document in use for all modern aircraft.

Optimisation of Maintenance




MSG-2 – Bottom-Up Process
Major Division
Structures
Systems
Powerplant
System A
System A
MSG-2 did not differentiate between maintenance being done for safety reasons versus economic reasons. The program became difficult to manage because it required so many components to be individually tracked.
Subsystems
Assemblies
Components
MSG-3 – Top-Down Process
System
System A
Under MSG-3 logic, maintenance tasks are separated into safety and economic categories, and these activities are assessed at the system level rather than the component level.
Subsystems
Assemblies
Components

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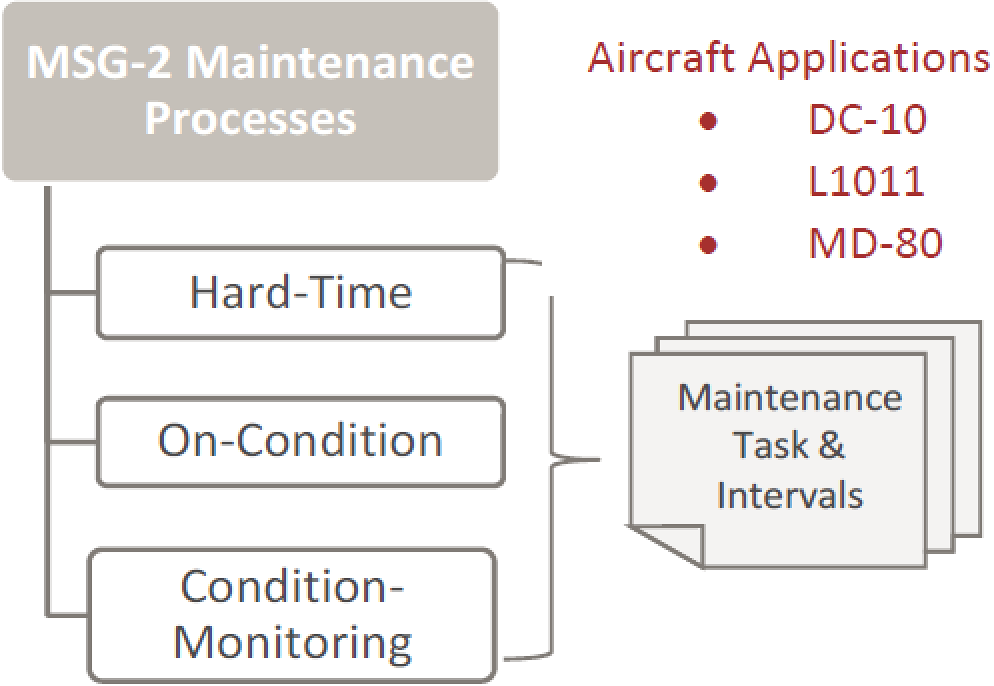
MSG-2



Aircraft Applications:

- DC-10
- L1011
- MD-80

MSG2 original definitions

→ Maintenance programs generally include one or more of the following primary maintenance processes:

- <u>Hard Time Limit (HT)</u>:
  A maximum interval for performing maintenance tasks. These intervals usually apply to overhaul, but also apply <u>to total life of parts or units.</u>
- <u>On Condition (OC)</u>:
  Repetitive inspections, or tests to determine the condition of units or systems or portions of structure (Ref.: FAA Advisory Circular 121-1).
- <u>Condition Monitoring (CM)</u>:
  For items that have neither hard time limits nor on condition maintenance as their primary maintenance process. Condition monitoring is accomplished by appropriate means available to an operator for finding and resolving problem areas.

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FAA AC 120-17A Definitions

- (1) Hard-Time (HT). This is preventive primary maintenance process. It requires that an appliance or part be periodically overhauled in accordance with the carrier's maintenance manual or that it be removed from service.
- (2) On-Condition (OC). This is a preventive primary maintenance process. It requires that an appliance or part be periodically inspected or checked against some appropriate physical standard to determine whether it can continue in service. The purpose of the standard is to remove the unit from service before failure during normal operation occurs.
- (3) Condition-Monitoring (CM). This is a maintenance process for items that have neither "Hard-Time" nor "On-Condition" maintenance as their primary maintenance process. CM is accomplished by appropriate means available to an operator for finding and solving problem areas. The detailed requirements for the condition-monitoring process are included as appendix 1 to this circular.

MSG2 – cont'd

- EASA in Part M uses the term CM as being preventive process and OC as being non-preventive which is oposite to the definition in the source MSG 2 document. This kind of interpretation is not rare and causes a lot of confusion in the industry.
- Per EASA interpretation,
  - Condition Monitoring is a preventive maintenance process. It requires that the component or a system be periodically tested and checked in accordance with defined standards and criteria, using adequate methods, to determine if the tested component/system is in condition that allows its operation untill next such scheduled inspection/test.
  - On Condition is not a preventive maintenance process, it allows failures to happen and relies on in-service data or pilots reports to determine and rectify existing faults.

MSG3 original definitions

The content of the scheduled maintenance itself consists of two groups of tasks

- a) A group of scheduled tasks to be accomplished at specified intervals. The objective of these tasks is to prevent deterioration of the inherent safety and reliability levels of the aircraft. The tasks in scheduled maintenance may include:
  - (1) Lubrication/Servicing (LU/SV or LUB/SVC)
  - (2) Operational/Visual Check (OP/VC or OPC/VCK)
  - (3) Inspection/Functional Check (IN*/FC or */FNC)
  - * General Visual Inspection (GV or GVI)
    * Detailed Inspection (DI or DET)
    * Special Detailed Inspection (SI or SDI)
    * Scheduled Structural Health Monitoring (S-SHM)
  - (4) Restoration (RS or RST)
  - (5) Discard (DS or DIS)

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MSG3 original definitions

- b) A group of non-scheduled tasks which result from:
  - (1) The scheduled tasks accomplished at specified intervals.
    (2) Reports of malfunctions (usually originated by the operating crew). (3) Data analysis.

The objective of these non-scheduled tasks is to restore the aircraft to an acceptable condition.

MSG – 2	MSG – 3
Separate analysis for: ➢ Systems ➢Structures	Separate analysis for: ➢ Systems ➢Structures ➢Zonal
Process Oriented	Task Oriented
Bottom-Up Approach **Airplane** ↑ **System** ↑ **Component** ↑ **Unit**	Top-Down Approach **Airplane** ↓ **System** ↓ **Component** ↓ **Unit**
Maintenance Process : HT / OV / CM ↓ Maintenance Task & Intervals	**Maintenance Tasks : LU, SV, OP, VC, IN, FC, RS, DS** ↓ Maintenance Task & Intervals

Contents of MSG-3 Document

- Working portions of MSG-3 are contained in the next four (4) sections.
  - Systems/Powerplant, including components and APU's, are considered in [Section 2-3].
  - Aircraft Structures is considered in [Section 2-4],
  - Zonal Inspections in [Section 2-5] and
  - L/HIRF is considered in [Section 2-6].
- Each section contains its own explanatory material and decision logic diagram (as appropriate); therefore, it may be used independently of other MSG-3 sections.

Systems/Powerplant Section

- Determination of MSI (Maintenance Significant Item):
  - ... process of identifying Maintenance Significant Items is a conservative process (using engineering judgment) based on the anticipated consequences of failure.
  - The top-down approach is a process of identifying the significant items on the aircraft at the highest manageable level.
- Determination of FEC (Failure Effect Category) – level 1
  - Safety (FEC 5), operational (FEC 6), economic (FEC 7), hidden safety (FEC 8) or hidden non-safety (FEC 9)
- Determination of applicable and effective maintenance tasks – level 2
- Definition of task intervals

Aircraft Structures Section

- Requirements for detecting:
  - Accidental Damage (AD),
  - Environmental Deterioration (ED),
  - Fatigue Damage (FD), and
  - procedures for preventing and/or controlling corrosion

  form the basis for the MRB structural maintenance.
- Determination of SSIs (Structure Significant Items):
- „A Structural Significant Item (SSI) is any detail, element or assembly, which contributes significantly to carrying flight, ground, pressure or control loads, and whose failure could affect the structural integrity necessary for the safety of the aircraft."

Zonal Inspection Section

- The Zonal Inspection Program (ZIP) provides for the consolidation of a number of General Visual Inspection (GVI) tasks for each zone.
- The ZIP contains a series of GVI tasks generated from standard zonal analysis procedures. Detailed inspection (DET) and Special Detailed Inspection (SDI) are not to be contained in the ZIP.
- The ZIP contains GVI tasks derived from EZAPs as well as standard zonal analysis procedures. EZAP (Enhanced Zonal Analysis Procedures) takes into account zones with wiring/combustible material mix (EWIS).

L/HIRF Protection Analysis

- In order to narrow the focus of the analysis, the following concepts are accepted:
  - All visible L/HIRF protection (wires, shields, connectors, bonding straps, or raceways between connectors or termination points) may be covered by the Zonal Inspections.
  - L/HIRF protection within conduit or heatshrink, is covered in the Zonal Inspections by confirming integrity of the protective covering.
  - Inherent conductivity of the aircraft structure is covered by the Zonal Inspections. Corrosion concerns are addressed by the Structural Inspections.
  - Composite fairings with conductive mesh are covered by the Zonal Inspections.
  - Where the Zonal Inspections are not effective, additional analysis may produce other scheduled maintenance tasks.

Airworthiness Limitations

- AWLs are items that the type certification process has defined as critical from a fatigue or damage tolerance assessment.
- The inspection frequency of such items is mandatory and they should be treated in the same way as a CMR*
- AWLs are:
  - Life Limits - Approved mandatory replacement times for life limited components,
  - ALI inspections - Approved mandatory structural inspections and related intervals,
  - Critical design configuration control limitations (CDCCL) – Approved mandatory tasks related to fuel tank safety.

Certification Maintenance Reqirements

- Tasks determined within the type certification process (independently of MRB process) that represent items critical for airworthiness.
- They are published in CMR Document by the aircraft type certificate holder.
- There are two types of CMR tasks:
  - CMR* ("One Star Tasks") – prescribed task interval can be extended only by type certifying authority based on the recommendation of type certificate holder.
  - CMR** ("Two Star Tasks") – prescribed task interval can be extended or approved to be extended by authority of the state of the aircraft register.

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SECTION 2: CMR "TWO STAR" TASKS

MSI	MSI AND TASK DESCRIPTION	INTERVAL
21.28.00 21.43.00	CARGO COMPARTMENT, VENTILATION, HEATING, AND GROUND COOLING SYSTEM	
	Operational test of ground cooling isolation valve to verify closing in case of smoke warning (MRB Report task 2128/4300-4) (Task applicable only if cargo compartment ground cooling system is installed)	6000 FH
24.20.00	AC GENERATION	
	Operational test of static inverter (A319 and A321) (MRB Report task 242000-2a)	500 FH
26.16.00	CARGO COMPARTMENT SMOKE DETECTION (If installed)	
	Operational test of cargo compartment smoke detection by CFDS to confirm isolation valve latching circuit integrity (MRB Report task 261600-2)	450 FH
26.23.00	CARGO COMPARTMENT FIRE EXTINGUISHING (If installed)	
	Check firing circuit continuity (MRB Report task 262300-3)	8000 FH
	Check fire extinguisher lines for leakage and obstruction (MRB Report task 262300-4)	14000 FH
27.40.00	TRIMMABLE HORIZONTAL STABILIZER (THS)	
	Operational test of THS actuator with individual hydraulic systems (MRB Report task 274000-1)	400 FH
	Operational test of THS actuator jamming protection device (MRB Report task 274000-2)	4000 FH

Service Bulletins (SB)

- Aircraft manufacturers, engine manufacturers or component manufacturers are publishing Service Bulletins which contain:
  - approved aircraft, powerplant or component modification procedures and/or
  - additional inspections – inspection procedures
- Service Bulletins for the aircraft are published in one of four versions:
  - Alert, Mandatory, Recommended i Optional.
- Service Bulletins classified as Alert i Mandatory <u>are not mandatory unless they are requested by adequate AD Note</u>.
- Service Bulletins classified as Recommended have the status of recommendation and SBs classified as Optional are usualy developed for specific Operator on his request.

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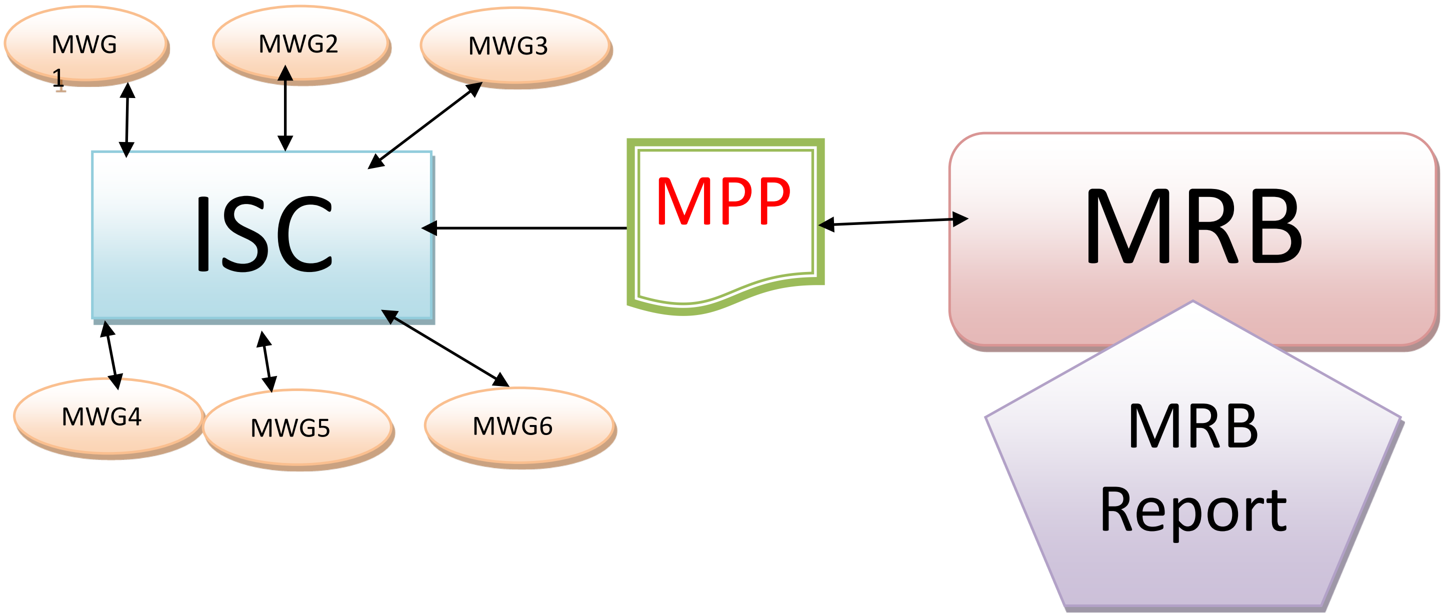
Airworthiness Directives - AD Note

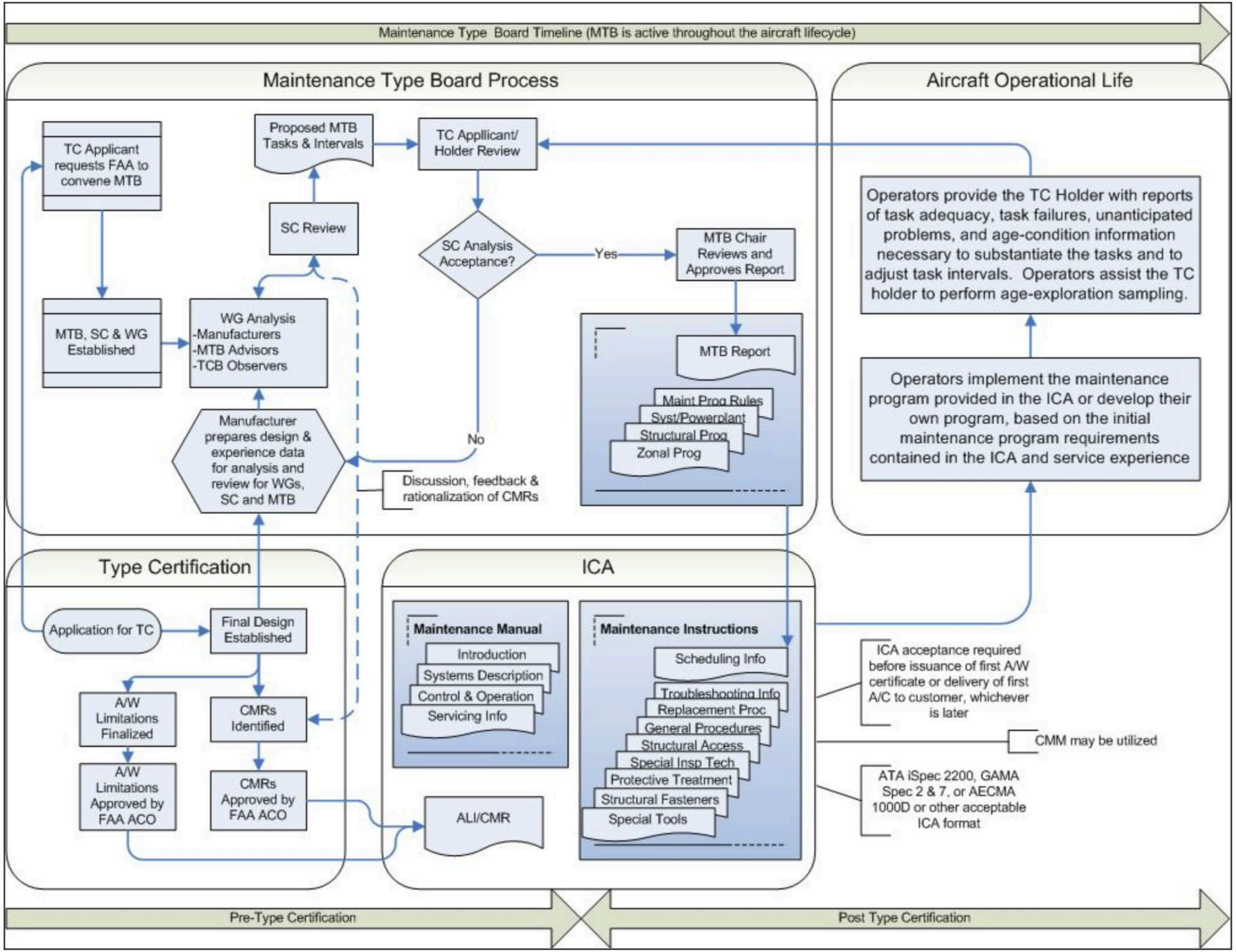
- Civil Aviation Authorities and type certifying Authority in particular may publish AD whenever there is a need to perform certain modification or maintenance task to maintain or recover airworthiness of an aircraft type, a group of the aircraft or a single aircraft.
- Such AD can mandate: a one time action, a repetitive action or a combination of the two.
- Aircraft operator is responsible to implement the AD whithin the deadlines as specified in the AD.
- All repetitive AD's have to be introduced in Maintenance Program.

MRBR – Maintenance Review Board Report

- MRBR contains the regulatory minimum scheduled tasking/interval requirements for a particular aircraft and on-wing engine maintenance programs.
- It is based on the Maintenance Planning Proposal that is developed by the Industry Steering Commitee (ISC).
- ATA MSG3 analysis process and procedures is being used for the development of an MRBR for all new aircraft or engines.
- The development of MRBR goes in parallel with Type Certification process
- In general, MRBR contains the same sections as MSG3 Document

Process of the MRBR development





Maintenance Type Board Timeline (MTB is active throughout the aircraft lifecycle)
Maintenance Type Board Process
Aircraft Operational Life
TC Applicant requests FAA to convene MTB
Proposed MTB Tasks & Intervals
TC Appllicant/ Holder Review
SC Review
SC Analysis Acceptance?
Yes
No
MTB Chair Reviews and Approves Report
MTB, SC & WG Established
WG Analysis
-Manufacturers
-MTB Advisors
-TCB Observers
MTB Report
Maint Prog Rules
Syst/Powerplant
Structural Prog
Zonal Prog
Manufacturer prepares design & experience data for analysis and review for WGs, SC and MTB
Discussion, feedback & rationalization of CMRs
Operators provide the TC Holder with reports of task adequacy, task failures, unanticipated problems, and age-condition information necessary to substantiate the tasks and to adjust task intervals. Operators assist the TC holder to perform age-exploration sampling.
Operators implement the maintenance program provided in the ICA or develop their own program, based on the initial maintenance program requirements contained in the ICA and service experience
Type Certification
ICA
Application for TC
Final Design Established
A/W Limitations Finalized
CMRs Identified
A/W Limitations Approved by FAA ACO
CMRs Approved by FAA ACO
Maintenance Manual
Introduction
Systems Description
Control & Operation
Servicing Info
Maintenance Instructions
Scheduling Info
Troubleshooting Info
Replacement Proc
General Procedures
Structural Access
Special Insp Tech
Protective Treatment
Structural Fasteners
Special Tools
ALI/CMR
ICA acceptance required before issuance of first A/W certificate or delivery of first A/C to customer, whichever is later
CMM may be utilized
ATA iSpec 2200, GAMA Spec 2 & 7, or AECMA 1000D or other acceptable ICA format
Pre-Type Certification
Post Type Certification

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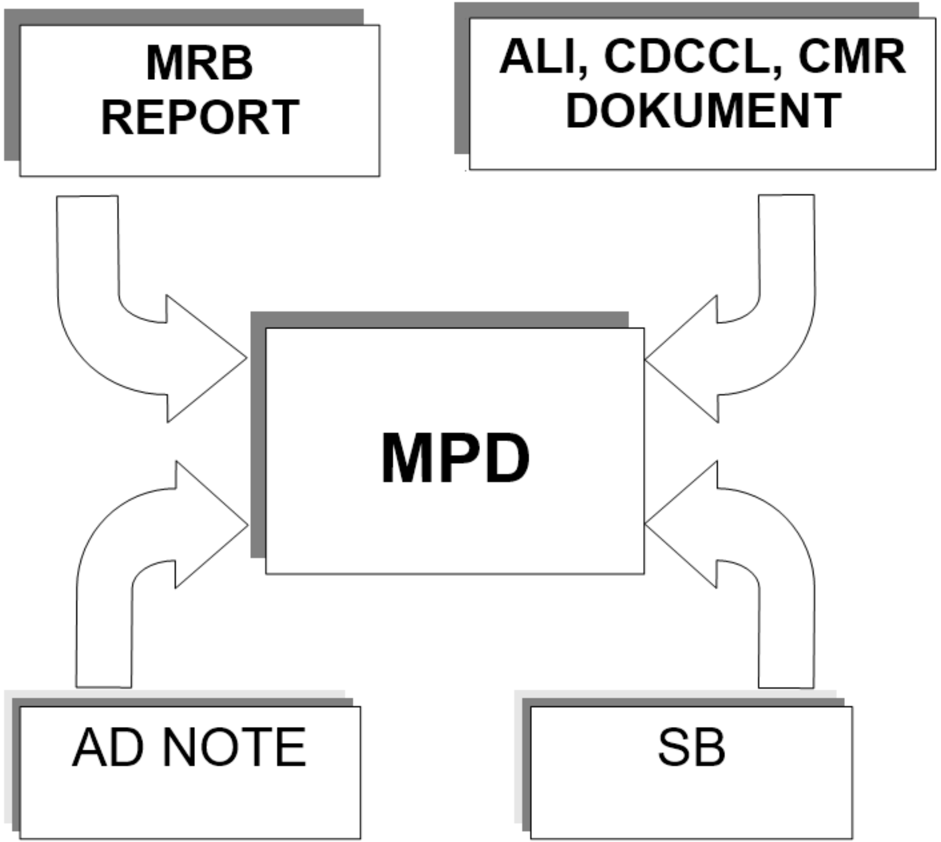
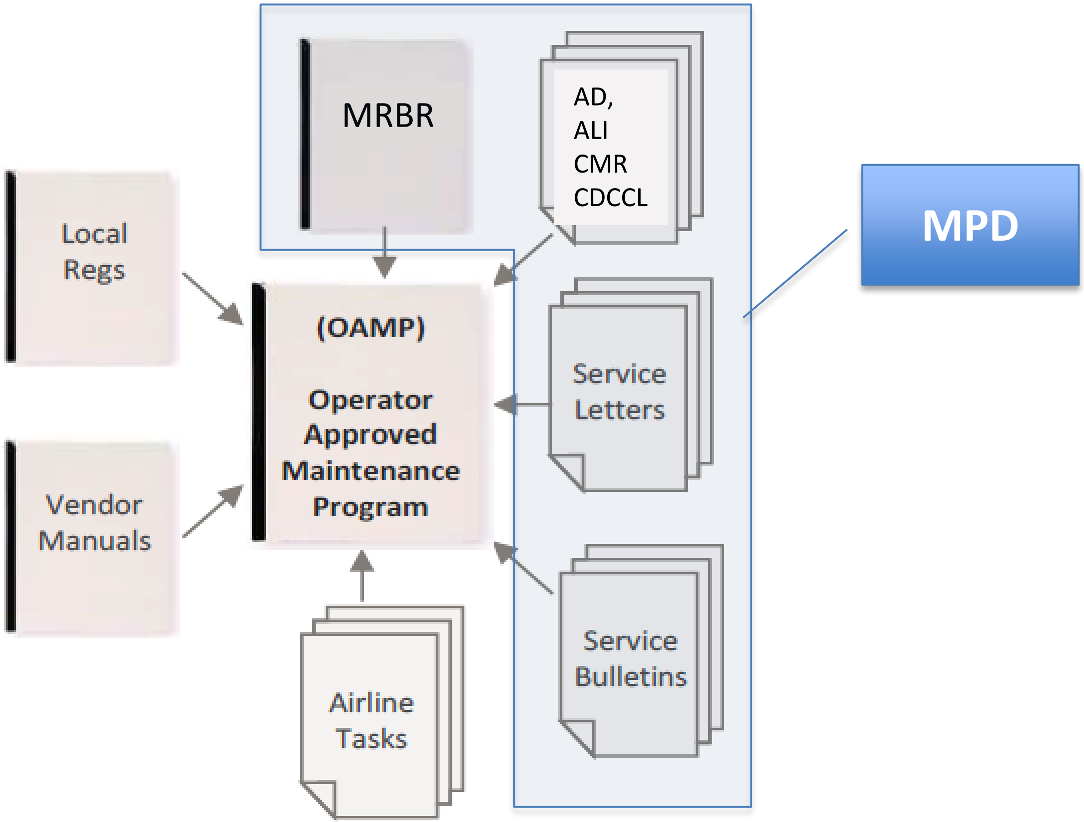
Maintenance Planning Document

- MPD is a publication issued by type certificate holder and it represents compilation of all requirements that need to be implemented in the Aircraft Maintenance Program. It is treated as the recommendation to the operators and it is not considered as mandatory.
- It is also linked with AMM, SRM and other manufacturer's manuals and publications using ATA 100/AMTOSS system of task numbering

Integration of sources in MPD



The content of the Operator's AMP



Links to the Example Documents

- → MSG2 (AC120-17A)
- → MSG3 (Rev2009)
- → MRBR Procedure (AC121-22C)
- → A340 MRBR (Rev11)
- → A320 MPD (Rev48)
- → Ageing Aircraft Programs
- → Operators Aircraft Maintenance Program

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AOC Certification

Omer Pita and Salvador Alepuz
Airworthiness Experts

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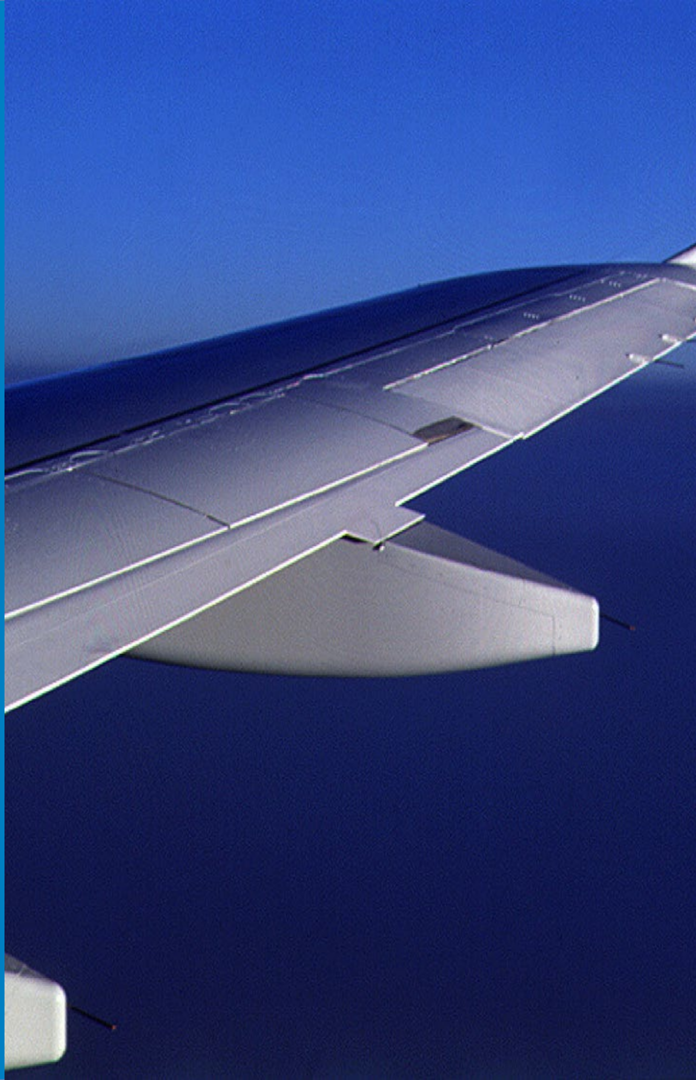
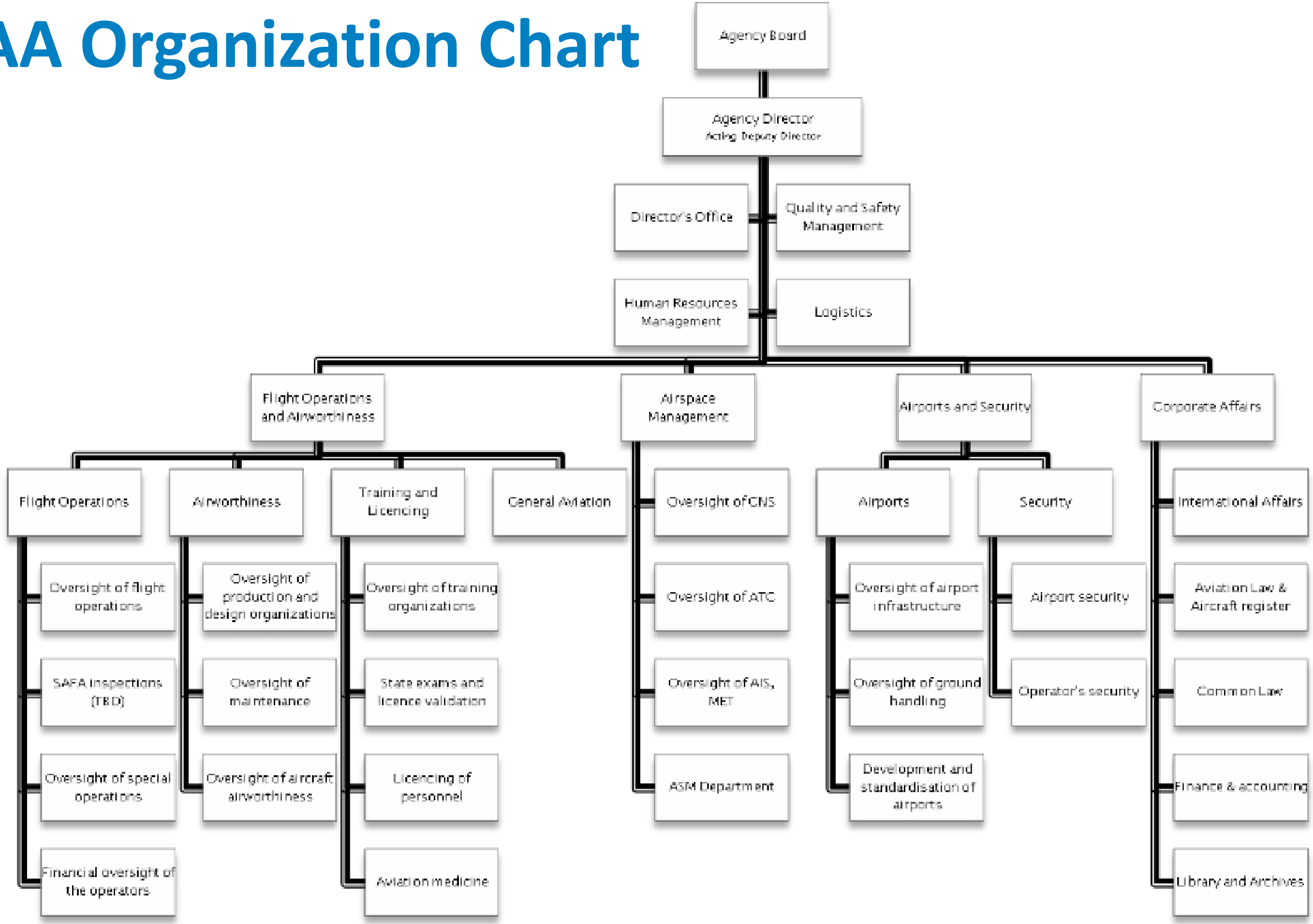
Role of CAA and Generic Certification Process



Civil Aviation Authority

- An civil aviation authority (CAA) is a government statutory authority in each country that regulates, certifies and oversees civil aviation with emphasis on aviation safety.
- NAA's typically regulate, certify and oversee the following critical aspects of civil aviation:
- Design of aircraft, engines, airborne equipment and ground-based equipment affecting flight safety
- Conditions of manufacture and test of aircraft and equipment
- Maintenance of aircraft and equipment
- Operation of aircraft and equipment
- Licensing of pilots, maintenance engineers, ATC controllers
- Airports and navigational aids
- Airspace usage, Aeronautical services (ATC, AIS, MET, CNS…)

Typical CAA Organization Chart



Core Processes of a CAA

- National Civil Aviation Authorities have three essential core processes that are of outmost relevance to certified organizations in civil aviation:
  - Rulemaking
  - Certification
  - Safety Oversight
- All three processes have to be carried out in accordance with international standards and recommended practices such as ICAO Annexes and Documents (see ICAO Doc 9734 Safety Oversight Manual).
- In EASA system of regulations, each Part has a section that defines Authority Requirements which have to be complied by Member State CAA

CAA Certification Function

- National Authorities are empowered by the State to act as sole authorized („accredited”) certification body for organizations involved in civil aviation.
- The role of CAA is analogue to the role of accredited ISO certification bodies with some major differences:
  - By regulation, certification of relevant aviation organizations (operators, airports, maintenance organizations, ATC providers…) is compulsory, while ISO certification is voluntary
  - ISO certification is commercial activity offered on the market, while certification of aviation organizations is non-commercial state activity
- Civil aviation safety regulations are analogue to ISO9000 standards, but are specific for aviation as opposed to generic and universal character of ISO9000 standards.

Role of CAA in International Context

- As a signatory to the ICAO Convention on International Civil Aviation, every ICAO (UN) Member State has an obligation to promulgate regulations and standards in accordance with the ICAO Standards and Recommended Practices (SARPs) as outlined in the ICAO Annexes.
- In order to discharge its responsibility, the State has to enact the aviation law that provides for the development and promulgation of State regulations consistent with ICAO Annexes.
- The State regulatory system enables the State to maintain continuing regulation and oversight of the activities of air operators without unduly inhibiting the operator's effective direction and control of the organization.

Importance of AOC

- An essential element in the regulatory system is the certification of air operators.
- In order to assess the competence of an air operator to provide a safe and regular service, the State should carefully examine the proposed operation, covering at least:
  - the organization and its processes and procedures,
  - staffing,
  - equipment,
  - proposed routes,
  - level and type of service and
  - finances.

Importance of AOC

- The issuance of an AOC is dependent upon the operator demonstrating compliance with regulations and fitness to safely carry the operations specified.
- Through the issuance of an AOC State ensures the protection of public interest.

International Aspect of the AOC

- The AOC and the associated operations specifications issued to an air operator are also intended to provide a basis for another State to authorize such air operator's operations in its territory (hence mandatory compliance of the state with ICAO SARP-s defined in ICAO Annex 6 – the global standard)
- Many states have enacted national regulations that regulate approval of foreign operator's operations on international flights on their territory/airspace.
- One important aspect in approving the operation of foreign operators is the credibility of the CAA who issued the AOC.

Airworthiness Considerations within the AOC Certification

- → A major consideration in the airworthiness review during the AOC certification process is to determine the capability of the applicant to adequately maintain its aircraft in airworthy condition continously, throughout the operation.
- → Consequently, the State shall conduct detailed evaluation and inspection of the applicant's maintenance organization, maintenance control manual, maintenance programme, staffing, facilities, training and ability to carry out day-to-day operations.
- → The airworthiness inspections and evaluations should be carried out under the overall coordination of an inspector in charge of the certification team of the air operator.

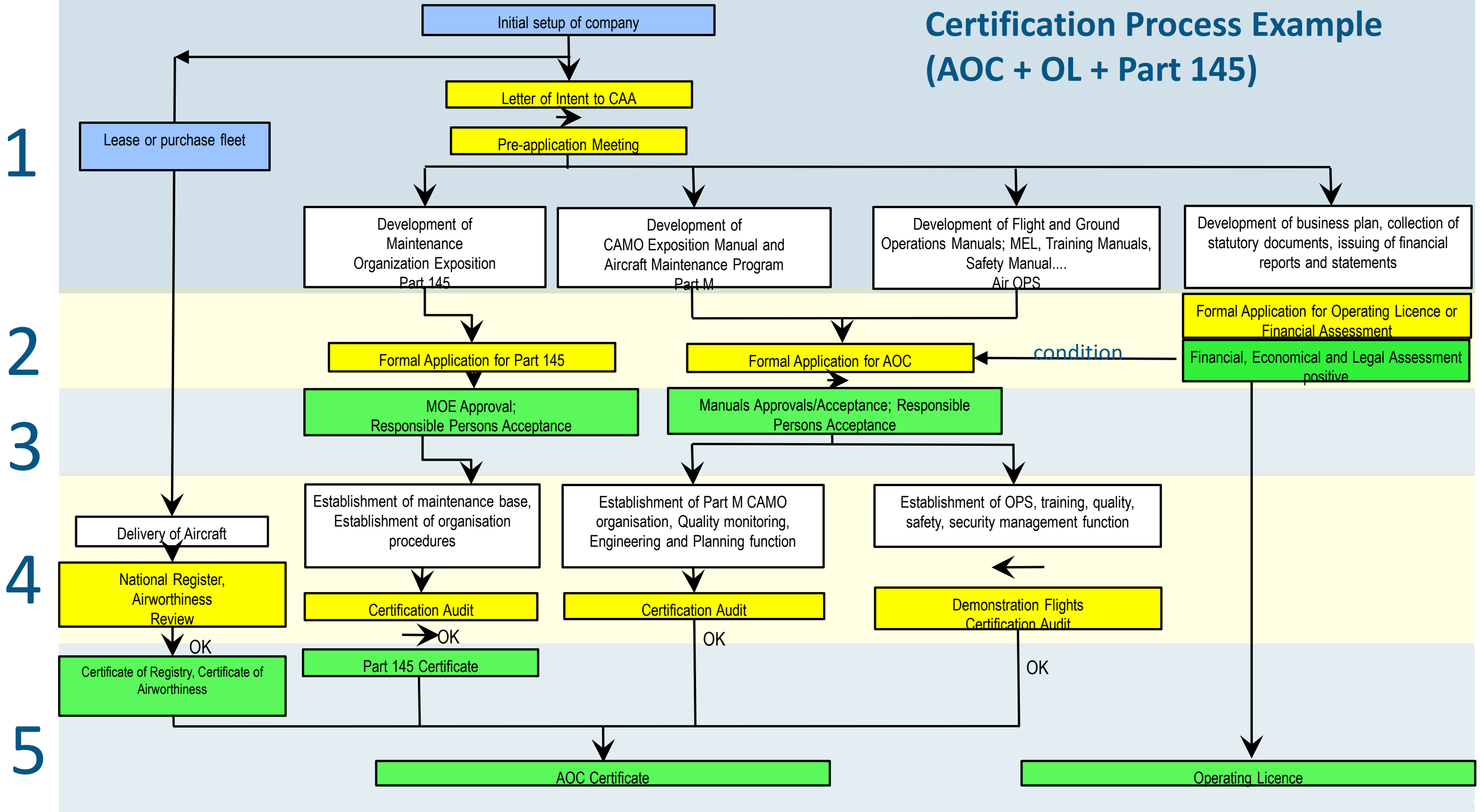
AOC-Airworthiness Certification Package

- During the AOC certification, it is to be expected that following distinct certification processes will be utilized:
  - Registration of the aircraft, followed by the Airworthiness Review and issuing of the Certificate of Airworthiness (CofA) – will take place in case that operator has acquired the aircraft which is not already registered in national register
  - Certification of operator's Maintenance Control capability – integral part of AOC Certification (in EASA environment it is CAMO/Part M Approval)
  - Certification of the Approved Maintenance Organization – in case that operator intends to carry maintenance of its aircraft (it can be in various scope)
- Operators may have an Approved Maintenance Organization (AMO) as part of their organization or the maintenance of its aircraft may be contracted to an AMO approved for the purpose. In issuing the AOC, CAA will have to be satisfied that.

Certification Procedure

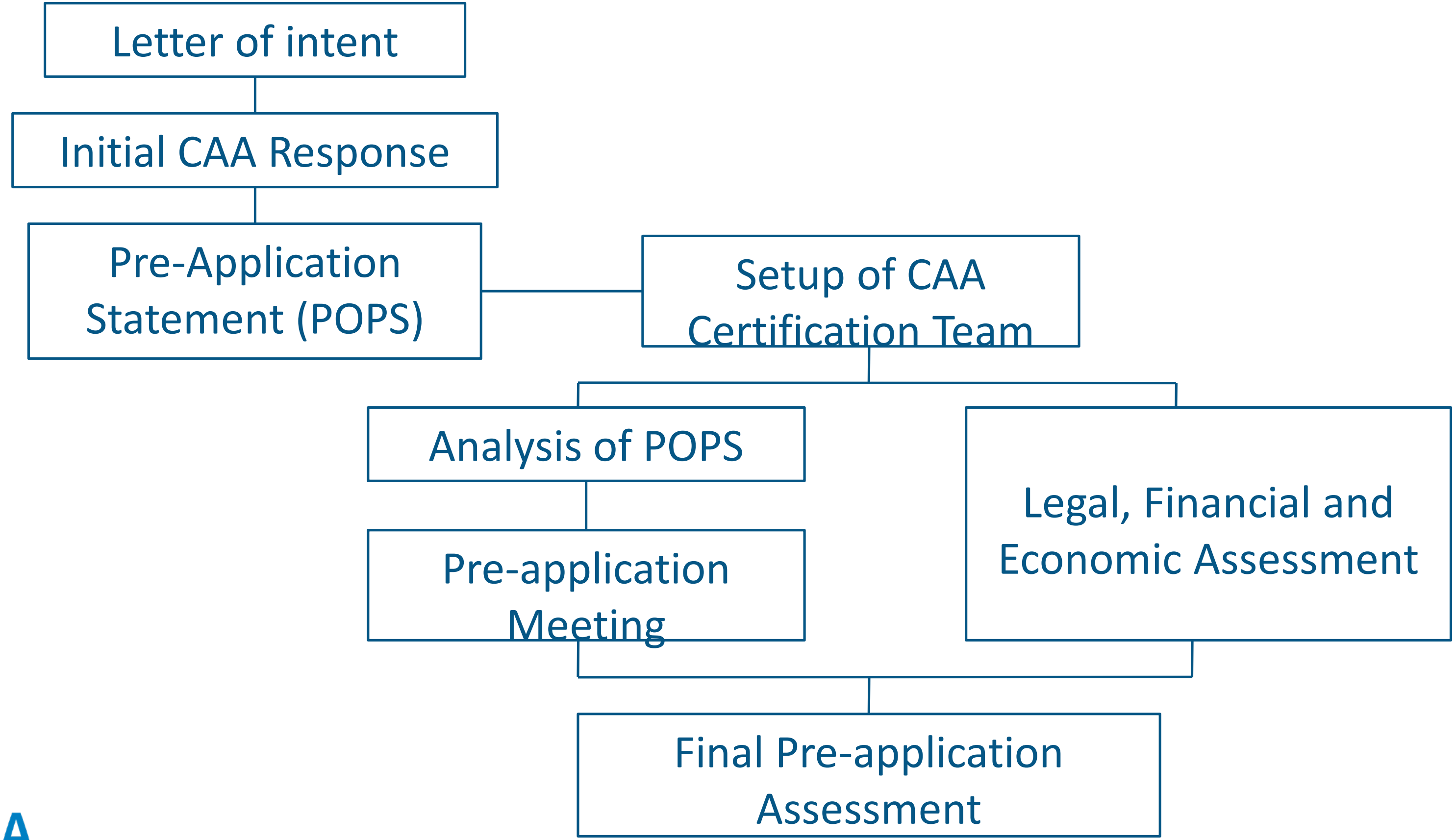
- The procedure for the application and granting of an AOC should be organized in phases and normally will take the following sequence:
  - pre-application phase;
  - formal application phase;
  - document evaluation phase;
  - demonstration and inspection phase; and
  - certification phase.

Certification Process Example (AOC + OL + Part 145)



EASA

Generic Flow of Pre-application Phase



Pre-application Phase

- A prospective operator who intends to apply for an AOC shall enter into preliminary discussions with CAA by expressing the interest in starting-up an airline.
- Normally, this is best done by the Letter of Intent or similar document, but can be done by phone call or other means.
- Example LoI

CAA Response to Expressed Intent

- CAA shall acknowledge expressed intent of the applicant and provide initial AOC information package containing advisory material and guidance concerning the applicable regulations and the description of certification process
- The initial information package should include:
  - a form for the prospective operator’s pre-assessment statement (POPS) to be completed by the applicant and
  - an advisory pamphlet containing:
  - a description of the application process for obtaining an AOC;
  - an introduction to the specific relevant regulations;
  - guidance on the evaluation of an applicant for certification;
  - guidance on the issuance of an AOC and associated operations specifications; and,
  - instructions for completing the POPS form

Purpose of Pre-assesment Statement

- The purpose of the POPS is to confirm the intent of the applicant to continue with the process for certification and to provide essential preliminary information about the intended operations in a structured manner,
- To activate CAA to formally start the process,
- To enable preliminary assessment of the applicant and
- To give sufficient information to start preliminary planning of the resources depending on the extent and scope of the planned AOC
- POPS example

CAA Actions on Receipt of a Completed POPS

- Once a completed POPS is received, a senior CAA inspector will be appointed as the project manager (PM) and
- a certification team will be established consisting of qualified and experienced inspectors of the necessary specializations, such as operations, airworthiness, cabin safety, and dangerous goods.
- CAA certification team will conduct a review of the POPS and if the information provided is considered acceptable, the PM will schedule a pre-application meeting with the applicant.

Role of Certification Project Manager

- The PM shall serve as the Focal Point for CAA throughout the certification process.
- The PM must thoroughly co-ordinate all certification matters with all other specialists assigned to the certification project.
- The PM shall be responsible for ensuring that all certification job functions are completed.
- All correspondence, both to and from the applicant, shall be coordinated with the PM.
- The PM shall ensure that CAA and the air operator staff involved with the certification project are kept fully informed of the current status of the certification.
- The PM must notify CAA management of any information that may significantly affect or delay the certification project.

POPS Analysis - Preparation for Pre-application Meeting

- Thorough and careful preliminary assessment of the applicant is important to prevent future problems.
- CAA has to make sure that in this preliminary phase:
  - The applicant's competence is established,
  - Assessment has been done of the financial, economic and legal status of the applicant,
  - Assessment of the proposed operation has been done,
  - The financial viability of the operation has been assessed,
  - Proposed arrangements for the purchase or lease of aircraft and major equipment are viable.

Pre-application Meeting

- The purpose of the pre-application meeting is to confirm the information provided in the POPS to determine whether or not the applicant has sufficient knowledge of the appropriate national regulations and requirements and to confirm, for the applicant, the expectations of CAA.
- The pre-application meeting will be attended by the CAA PM and certification team and the key management personnel of the applicant. The applicant should be prepared to discuss, in general terms, all aspects of the proposed operations.

Pre-application Meeting cont’d

- The applicant will be provided with an overview of the certification process and
- made aware of the State procedure dealing with assessment of financial, economic and legal matters, and for the necessary assessment of the applicant’s financial resources and ability to support the proposed operations.
- It is essential that the financial, economic and legal assessments are commenced early since an AOC shall not be granted without a satisfactory assessment of these aspects from the appropriate department.
- In EASA/EU environment, financial assesment is done through the process of issuing the Operating Licence

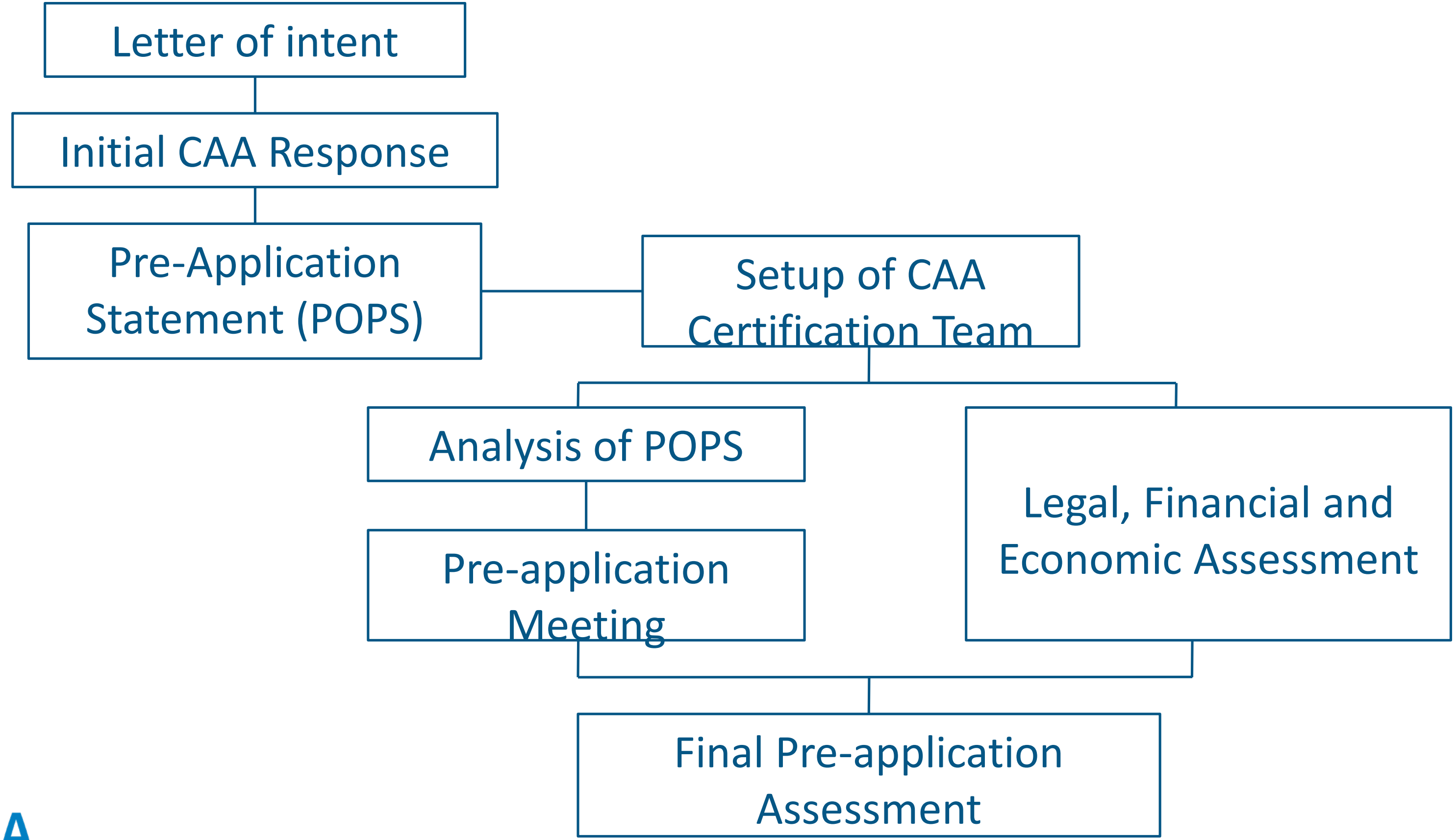
Pre-application Meeting

- In response to the expressed intentions, CAA has to make sure that:
  - Potential applicant is provided with complete information concerning the type of operations which may be authorized, the data to be provided by the applicant and the procedures which will be followed in the processing of the application.
  - It is essential that the applicant has, in this pre-application phase, a clear understanding of the form, content and documents required for the formal application.
  - CAA should advise the prospective operator on the approximate period of time that will be required to conduct the certification process, subsequent to the receipt of a complete and properly executed application. This advice is of particular importance so that such applicants may avoid undue financial outlays during the certification period.

Pre-application Meeting Record

- The Pre-Application Meeting should be documented by Minutes of Meeting or similar structured form intended for that purpose.
- Based on the results of the Meeting and mutualy agreed tentative certification timeline, CAA should make tentative timeline and plan the resources (human, financial, material…) that will be used for the purpose of certification.
- Example form

Pre-application Generic Flow Repeated



Formal Application Phase

- Upon completion of the assessment concerning the financial, economic and legal aspects of the application and after any deficiencies have been corrected, a provisional determination shall be made regarding the general feasibility of the operation.
- If the operation is found to be provisionally acceptable, the second phase of the certification process, the formal application phase, can be undertaken.
- The formal application for an AOC, normally should be accompanied by the full set of required documentation, but sometimes it is practical that some manuals/documents are submited later in the process.

Meaning of the Formal Application

- The submission of a formal application is to be interpreted by CAA to mean that the applicant:
  - is aware of the regulations applicable to the proposed operation,
  - is prepared to show the method of compliance and
  - is prepared for an in depth evaluation, demonstration and inspection related to the required manuals, training programmes, operational and maintenance facilities, aircraft, support equipment, record keeping, dangerous goods programme, security programme, flight crew and key management personnel, including the functioning of the administrative and operational organization.
- Formal Application without the applicant actually being ready, can easily result in uncontrolled certification process and can waste a lot of time and resources both from applicant and CAA

Formal Application Package

- → The formal application for certification can be in a form of an application letter or a dedicated application form.
- → In both cases it should be accompanied with attachments containing the information required by CAA.
- → The development of the application letter and its attached documents should have been coordinated with the CAA certification team subsequent to the pre-application meeting, with the aim to improve quality of the application package.
- → The fee for the certification of an air operator shall be submitted when the operator submits the formal application package.

Contents of the Application Letter

→ The application letter shall be signed by the applicant’s accountable executive and shall contain at least the following information:

a) a statement that the application serves as a formal application for an AOC;

b) the name and address of the applicant;

c) the location and address of the applicant’s principal place of business and the main base of operations;

d) a description of the applicant's business organization and corporate structure, names and addresses of those entities and individuals having a major financial interest;

e) the name and address of the applicant’s legal representative;

f) the identity of key management personnel

g) the nature of the proposed operations: passenger/cargo, day or night, visual flight rules (VFR) or instrument flight rules (IFR), whether or not dangerous goods are to be transported; and

h) the desired date for the operation to commence.

Required Attachments to the Application Letter

→ The attachments that need to accompany the formal application letter are:

a) the identification of the operation specifications sought with information on how associated conditions will be met;
b) the schedule of events in the certification process with appropriate events addressed and target dates;
c) an initial statement of compliance or detailed description of how the applicant intends to show compliance with each provision of the air navigation regulations;
d) the management structure and key staff members including titles, names, backgrounds, qualifications and experience, with regulatory requirements satisfied;
e) the details of the SMS;

Attachments to the Application Letter – cont'd

f) a list of designated destination and alternate aerodromes for scheduled services, areas of operation for non-scheduled services and bases for operations, as appropriate to the intended operations;

g) a list of aircraft to be operated;

h) documents of purchase, leases, contracts or letters of intent;

i) arrangements for crew and ground personnel training and qualification, facilities and equipment required and available;

j) the operations manual;

k) the maintenance control manual (MCM);

l) details of the method of control and supervision of operations to be used; and

m) the status of the assessment of financial, economic and legal matters by the appropriate government department.

M.B.701 Application; Regulation (EU) 2015/1536

a) For licenced air carriers in accordance with Regulation (EC) No 1008/2008 the competent authority shall receive for approval with the initial application for the air operator's certificate and where applicable any variation applied for and for each aircraft type to be operated:

1. the continuing airworthiness management exposition;
2. the operator's aircraft maintenance programmes;
3. the aircraft technical log;
4. where appropriate the technical specification of the maintenance contracts between the CAMO and Part-145 approved maintenance organisation.

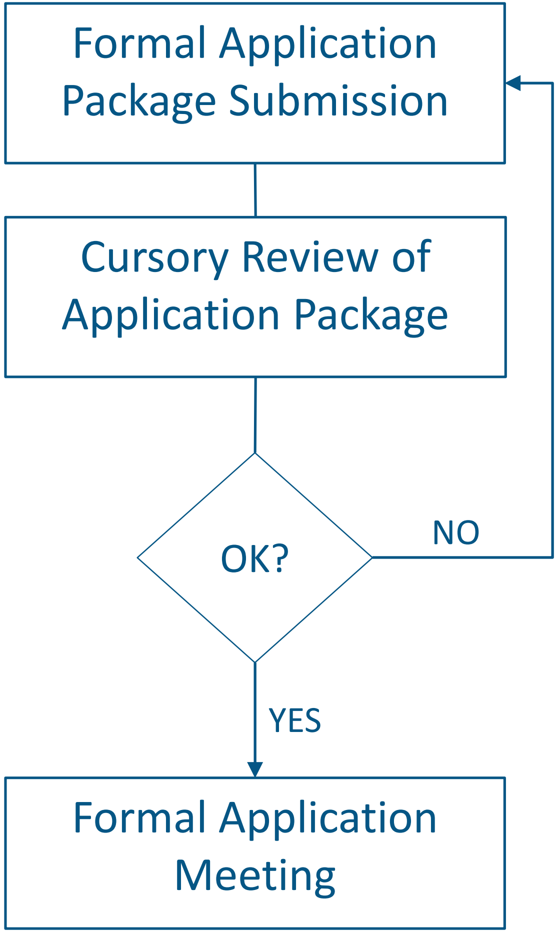
Cursory Review of the Formal Application Package

- CAA certification team will make a cursory review of the formal application package to check that the required attachments have been presented, that these attachments address the required information and that the documentation is of an appropriate quality.
- If the formal application package is incomplete or otherwise unacceptable, the PM shall inform the applicant in writing, providing details of the deficiencies and advice on the resubmission of the formal application.
- If the information in the formal application package is considered acceptable by the certification team, the PM will schedule a formal application meeting with the applicant.
- Appropriate record of this review shall be made to document the acceptability of the formal package. Example: Formal Application Job Aid AOC-002

Formal Application Meeting

- A formal application meeting shall be conducted between the PM, the certification team and all the key management personnel of the applicant, with the objective of resolving any questions to establish a common understanding on the future procedure for the application process.
- Subsequent to the formal application meeting and subject to successful acceptance of the application package, the PM shall provide the applicant with a letter acknowledging receipt and acceptance of the formal application.

Application Phase Generic Flow



Document Evaluation Phase

- The document evaluation phase involves the detailed examination of all documentation and manuals provided by the applicant to establish that every aspect required by the regulations is included and adequately covered.
- In order to facilitate this phase of the certification process, the applicant shall coordinate all aspects of the development of the required documentation with CAA certification team, prior to submission of the formal application.
- If a document or manual is incomplete or deficient, or if non-compliance with regulations or safe operating practices is detected, the document or manual shall be returned to the applicant for corrective action with a detailed list of deficiencies..

Documents And Manuals To Be Evaluated

- **Draft operations specifications**
- Statement of compliance
- **Management personnel resumes** providing qualifications and aviation experience
- Aircraft flight manuals
- Operations manual (individual manuals: AOM, **MEL, CDL**… form part of the operations manual)
- SMS manual, including a description of the flight safety document system
- Security programme manual
- **Maintenance Control Manual (MCM, CAME, MME or similar)**
- **Maintenance programme for each aircraft type**

Airworthiness Related AOC Documents and Manuals To Be Evaluated

- **Maintenance Control Manual (MCM, CAME, MME or similar)** – pertaining to ICAO Annex 6/EASA Part M requirements.
- **Maintenance Organisation Exposition (MOE, MOM, MPM…) -** in case that operator requires AMO Approval (Part-145) to carry on maintenance.
- **Aircraft Maintenance Programme for each aircraft type**
  - Including **Maintenance Reliability Program**
- **Operations specifications – Special Approvals**
  - Performance based navigation (PBN), Reduced vertical separation minima (RVSM), Low visibility operations, Extended diversion time operation (EDTO)
- Operations manual (individual manuals: AOM, **MEL,** CDL… form part of the operations manual)
- **Management personnel resumes -** qualifications and aviation experience

→ Documents review/inspection shall be adressed in detail on separate course modules

Certification audits and Inspections

- → The applicant shall demonstrate to CAA that the processes and procedures described in the MCM are in place.
- → The AWI shuld conduct an inspection of the operator's maintenance control organization to verify the processes and procedures.
- → This should also include interviews with personnel to ensure that the procedures are transmitted and understood.

Certification audits and Inspections

- The applicant shall demonstrate to CAA that the processes and procedures described in the maintenance programme are in place.
- The AWI should conduct a review with the applicant to verify the processes and procedures.

Certification audits and Inspections

- The applicant shall demonstrate to [State CAA] that the processes and procedures described in the MCM and maintenance contract arrangements are in place.
- The AWI should conduct an inspection of the operator's maintenance control organization to verify the processes and procedures are in place and personnel aware of them.
- If the maintenance is contracted, ensure the existence of a contract covering all then maintenance activities.

Aircraft inspection (normally part of CofA process)

- The applicant should demonstrate to CAA that the aircraft it intends to operate is in compliance with the maintenance programme and CAA regulations. This should be done through the:
  - i) Review of maintenance records, if available
  - ii) Conduct of aircraft interior and external inspection
- Review of maintenance records would verify that all required maintenance, including any bridging check, has been carried out and in compliance with the maintenance schedule.

Aircraft inspection (normally part of CofA process)

- The AWI will conduct walkaround aircraft inspection(s) to verify that the required emergency and safety equipment, log books, documentation and decals and markings are present and meet CAA requirements.
- The exterior inspection should also identify any damages or leakages.
- The AWI should also conduct a sampling check on aircraft components to ensure that they comply with the approved aircraft configuration.
- The aircraft inspection should also verify that the equipment required for any special operations are installed.

Demonstration Flight

- The following factors will be considered when determining the demonstration flight requirement:
  - a) to what extent is the new aircraft substantially different from an aircraft previously flown by the applicant's flight crew (such as changing from turboprop to turbojet, unpressurized to pressurized, or narrow body to wide body);
  - b) to what extent is the applicant's route structure affected by the request (for example, inauguration of international routes and use of special areas of operation);
  - c) what is the experience level of personnel involved in the operation (for example, flight and cabin crewmembers' previous experience in the operation of this type of aircraft);
  - d) how does the applicant propose to conduct the proving flights (for example, a few long-range versus several short-range flights); and
  - e) what level of management experience exists in the company with this type or similar type or make of aircraft.

Demonstration Flight

- Airworthiness items on demonstration flights are:
  - The aircraft condition – walkaround by CAA inspector
  - Emergency equipment on board
  - Line maintenance performance
  - Aircraft documents and technical logs completion
  - MEL dispatch (if applicable)
  - Maintenance coordination

Demonstration Flight

- After the demonstration flights are completed, the operator will be provided with a detailed de-briefing and will be informed whether or not his overall performance was satisfactory or unsatisfactory.
- This will be followed with a letter detailing the same information.

Certification audits and Inspections

→ Airworthiness inspections ansd audits shall be addressed in detail on separate course modules

Certification Phase

- The certification phase is the conclusion of the certification process when CAA PM has determined that all certification requirements, both operational and economic, have been completed in a satisfactory manner and that the operator will comply with the applicable regulations and is fully capable of fulfilling its responsibilities and conducting a safe operation.
- The culmination of this phase is the issuance of the AOC and its associated operations specifications authorizing the conduct of the specified operations.

FINAL PREPARATION FOR THE ISSUANCE OF AN AOC

- The CAA PM will have notified the applicant in writing of all discrepancies that need to be resolved before an AOC and its associated operations specifications can be issued.
- The PM reviews the final operations specifications and makes any changes necessary.

FINAL PREPARATION FOR THE ISSUANCE OF AN AOC

- The PM and the CAA certification team shall ensure that all the requirements for certification have been met.
- Further, an AOC will not be issued until the State organization responsible for the economic and financial assessment of the applicant has presented a favourable report, and until CAA is satisfied that the operator has the financial resources to conduct its planned operations, including resources for the disruptions that can be reasonably expected in daily operations.

Certification Recommendation Report

→ The PM will provide a report with appropriate recommendations on the issuance or denial of an AOC to the State official responsible for its issuance. The report shall include the following information.

→ In the case of a recommendation on issuance of the AOC:

a) confirmation that the air operator has been certificated in accordance with the policy and procedures as contained in the [State] Air Operator Certification and Surveillance Handbook;

b) listing of the applicable job aids/checklists that have been completed to confirm that the air operator is in compliance with [State regulations] and related guidance material;

c) confirmation that [State CAA] is satisfied that the operator has the financial resources to conduct its planned operations;

d) signature of the PM and the name and title of each team member who assisted in the certification project.

Certification Recommendation Report cont'd

→ In the case of a recommendation on <u>denial</u> of an AOC:

a) listing of the applicable job aids/checklists that have been successfully completed to date;

b) details of certification requirements which the air operator has failed to achieve; and

c) signature of the PM and the name and title of each team member who assisted in the certification project.

ISSUANCE OF AN AOC

- CAA shall assign an AOC number and determine the date of issuance. The certificate and associated operations specifications shall be signed by the CAA official responsible for its issuance.
- The format and the content required for an AOC are provided in this example and this example
- A certification „master" check list shall be utilized and completed to confirm the completion of all certification activities prior to recommending issuance of the AOC and associated operations specification:
  EASA Form 13, EASA Form 6, ICAO AOC Checklist example

PERIOD OF VALIDITY OF AN AOC

- An AOC and associated operations specification shall be valid for the *period as defined in national regulations*. The date of issuance and an expiry date are to be entered on an AOC.
- Note*: If your State does not apply a period of validity to AOCs, amend the text as appropriate and add the following text … the fact that the certificate does not expire is indicated on the certificate.*
- In general, an AOC or any portion of an AOC issued by a CAA remains valid until:
  - a) CAA amends, suspends, revokes or otherwise terminates the certificate;
  - b) the AOC holder surrenders the certificate to CAA;
  - c) the AOC holder suspends operations for more than *the period defined in national regulations*; or
  - d) the expiry date, as applicable.

CAA Oversight Function

- Subsequent to the issuance of an AOC, CAA staff will be responsible for continued surveillance and for conducting periodic inspections to ensure the operator’s continued compliance with regulations, authorizations, limitations and provisions of its AOC .
- These periodic inspections are components of a continuing safety oversight programme.
- It is responsibility of CAA to perform continuous safety oversight of its certificate holders.
- Oversight has to be performed in accordance with international standards and it has to be continuous, planned and systematic.

CAA Oversight Function

- → Planned inspections have to cover all aspects of the regulation within certain period (2 years) and both announced and unannounced inspections have to be planned and carried out.
- → Inspected/audited organizations have to give CAA inspectors full access to all documents and all facilities in use.
- → CAA has legal authority to execute sanctions and legal proceedings against organizations and persons which do not comply with regulations (suspension or revocation of certificate, limitation of certificate, legal fines…)

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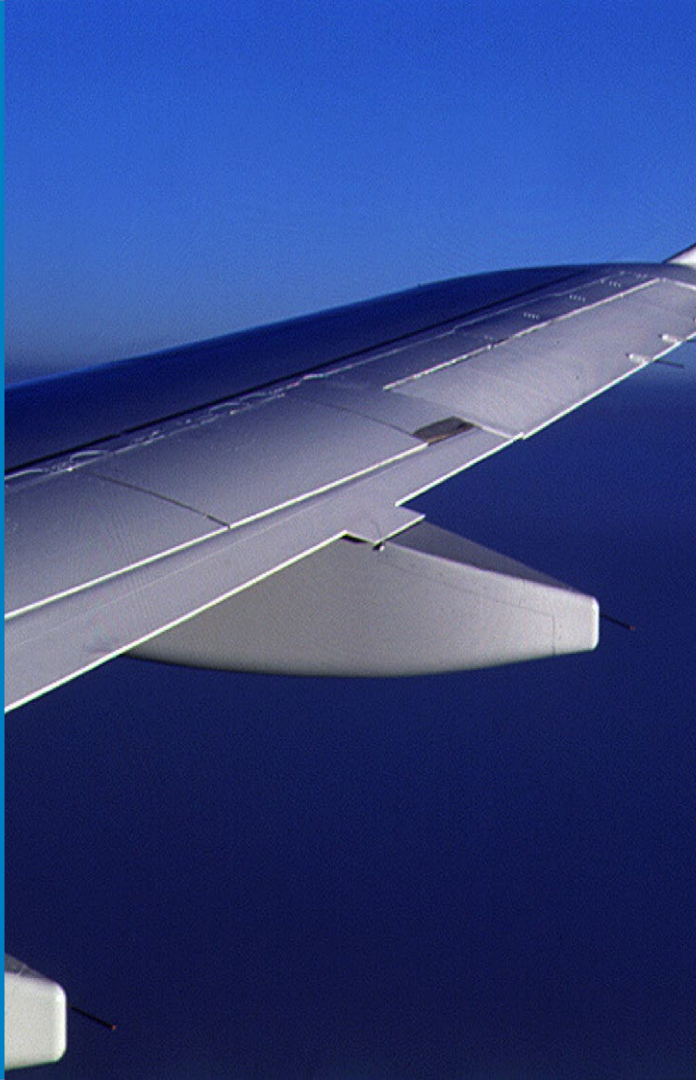
Approval of Documentation and Management Personnel



Airworthiness Related AOC Documents and Manuals To Be Evaluated

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- **Aircraft Maintenance Programme for each aircraft type**
  - Including **Maintenance Reliability Program**
- **Operations specifications – Special Approvals**
  - Performance based navigation (PBN), Reduced vertical separation minima (RVSM), Low visibility operations, Extended diversion time operation (EDTO)
- Operations manual (individual manuals: AOM, **MEL,** CDL… form part of the operations manual)
- **Management personnel resumes -** qualifications and aviation experience

Maintenance Control Manual (MCM)

- An AOC Applicant is required to prepare an acceptable MCM for the use and guidance of maintenance organization personnel.
- Accordingly, one of the first steps in the maintenance inspection is a thorough analysis of the MCM, the correction of any discrepancies and the tentative acceptance by the CAA inspector.
- During the course of the maintenance control inspection, the PM, assisted by qualified CAA airworthiness inspectors, shall determine that the provisions of the MCM are in place.
- The complexity of the MCM will vary depending upon the type, complexity and number of aircraft involved.

MCM Cont'd

- CAA shall accept/approve the operator's maintenance control manual (MCM) as required (in EASA Part M, approval of CAME is required).
- The MCM sets out the applicant's intentions and procedures with regard to maintaining the airworthiness its aircraft during its operational life. This applies whether or not the applicant for an AOC also intends to apply for approval as an AMO or intends to contract out maintenance to an AMO.
- The MCM, which may be issued in separate parts, shall be provided for use and guidance for maintenance and operational personnel as applicable.

MCM Cont'd

- The operator is accountable for the manual and is required to ensure that it is amended and revised as necessary. This is achieved by means of establishing a revision control system and ensuring that copies of any changes made be distributed to all holders of the manual.
- The design of the manual shall observe human factor principles including the proper use of written language, size of fonts and proper layout, use of diagrams, tables and charts where applicable.
- Link to EASA Part M CAME Requirements

CAA Administrative Procedure

- The assigned airworthiness inspector (AWI) shall use the check list like this example.
- All discrepancies must be addressed or actioned by the applicant to the satisfaction of the assigned AWI.
- The completed check list, all completed discrepancy reports, any correspondence with the applicant and any relevant documents in submitted conjunction with the application should be appropriately filed.
- A copy of the approved MCM shall be retained by CAA.

Layout and Presentation

- → A table of content referencing Chapters, Sections and page numbers of topics that are required in a MCM as per regulation.
- → The design and layout of the MCM observes human factor principles.
- → References to the appropriate forms to be used.

Description of Air Operator

- The legal (registered) name of the operator
- The full address, phone number(s), email and facsimile number(s).
- A description of the organization; its size, type and nature of business and type and number of aircraft to be operated.
- Geographic location of the office facilities and/or their operation's base when not co-located

Statement of Compliance

- Signed declaration by the accountable Manager that the MCM and other documents referenced in the MCM are in compliance with appropriate State regulations with the prescribed statement.
- May include a compliance matrix or chart.
- Provision for the MCM to be approved by CAA.

Revision and Distribution Control

- A list of effective pages (LEP) is used to ensure that every manual contains current information. The LEP shows the revision status of each page.
- Details the process of revising the MCM.
- The approval, control and distribution of a revision to the MCM.
- Description of how the MCM should be made available to each person who performs or manages a function that is described in the MCM or in any manual that is incorporated in the MCM.
- All copies of the MCM are serialized with a corresponding distribution list.

Key Roles and Responsibilities

- The names and titles of key persons assigned responsibilities.
- Details and descriptions of the function of each key assigned person.
- A company organization chart showing to whom each employee reports.

Approved Maintenance Programmes

- References made to the approved maintenance programme for each aircraft type operated.

Evaluation and review of policies, procedures and programmes contained in the MCM

- → To establish an evaluation programme to ensure that the approved policies and procedures contained in their MCM continue to comply with the regulatory requirements.
- → To include a system of analysis and continuing monitoring of the performance and efficiency of the maintenance programme(s).

Evaluation and review of policies, procedures and programmes contained in the MCM

- The evaluation programme (*In EASA environment: Quality System or Compliance Monitoring*) should review the entire maintenance control system, including but not limited to a periodic, recurring internal audit. An internal audit is intended to identify and document areas that fail to be effective in meeting regulations, standards and company policies and procedures.
- The evaluation programme should determine the root cause of deficiencies, areas of noncompliance, areas that need improvement, corrective actions needed and follow-up to ensure that the changes were effective.

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Regulatory and Technical Information *(EASA term: Maintenance Data)*

- A description that ensures any person who performs work and/or servicing has access to the latest applicable technical manuals, airworthiness directives, regulatory requirements or other related information.
- This system should include how technical and regulatory information is controlled for any work that is performed away from base.
- It should also address how these reference documents are controlled and updated.

Performance of Maintenance

- A description of the procedure to ensure the aircraft is maintained in accordance with the maintenance programme
- A description of the procedure for completing and signing a maintenance release for aircraft that had undergone maintenance.
- A description of the procedure that all modifications and repairs comply with airworthiness requirements.
- ref. EASA Part-M Subpart C, D, E;

Defect Control and Rectification

- A description of a system to control defects, including the rectification and deferral of defects.
- Policies and procedures for the use of an approved Minimum Equipment List (MEL).
- Identifying and handling recurring defects. This helps to avoid ineffective methods of repair and to ensure the defect will not reoccur

Maintenance Planning and Control

- A description of the procedures used to ensure that any maintenance tasks required by the maintenance programme, a mandatory continuing airworthiness information (MCAI), or any task required for the rectification of a defect is completed within the time constraints as approved by CAA.
- Planning and control system to track maintenance requirements to ensure that required intervals are not exceeded.

Maintenance Planning and Control

- The complexity of the system depends on the size of the air operator, the aircraft types and the number of aircraft operated. The system should be used to track the status of aircraft to forecast maintenance.
- A description of how alternate means of compliance are requested and complied with.

Maintenance Records

- A description of the kinds of technical records to be kept as required in regulation.
- Details of the methods used to record the maintenance, work or servicing performed, and ensure that any defects are recorded in the technical record
- A description of the procedures for technical record entries such as signing and dating entries, use of electronic records (where applicable), safe record keeping methods and the corrections and alterations to records.

Service Difficulty Reporting

- A description of the procedures used to report service difficulties in accordance with CAA regulations.
- Details of what needs to be reported by whom, when and in what format.

Maintenance Arrangements

- All maintenance contracts must be detailed in the MCM.
- Only approved maintenance organizations (AMO) or under an equivalent system acceptable to CAA can be contracted to carry out maintenance work.
- A description of what needs to be done before accepting an AMO. This would include procedures to ensure that the AMO has the necessary approvals and capabilities, facilities, equipment and manpower.
- If an AMO outside of State is to be used, additional requirements may need to be considered and applied.

Technical Dispatch

(In EASA environment: Line Maintenance Procedures)

- A description of technical dispatch procedures to ensure that aircraft are not operated unless they are airworthy, appropriately equipped, configured and maintained for their intended use. Technical dispatch procedures ensure that only those aircraft that conform to applicable airworthiness and operational requirements are dispatched.

Technical Dispatch
(In EASA environment: Line Maintenance Procedures)

- Procedures for the authorization and dispatch of aircraft for special operations including extended diversion time operation, reduced vertical separation minima operations, all weather operations, ferry flights and any other special operations.
- A description of a process to ensure all scheduled maintenance has been carried out and all MCAIs have been addressed or accomplished.

Personnel Training and Records

- A description of the training required for all personnel performing work. This would include the initial, recurrent and update training including: human factor training, CDCCL, Fuel Tank safety...
- A description of the kinds of personnel records to be kept as required in the regulation.
- Link to EASA CAME Requirements

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Evaluation of Management Personnel

Regulation (EU) No 1321/2014); Annex I (Part-M); SECTION A — TECHNICAL REQUIREMENTS:

- Nominated person or group of persons should have:
  - 4.1. practical experience and expertise in the application of aviation safety standards and safe operating practices;
  - 4.2. a comprehensive knowledge of:
    a) relevant parts of operational requirements and procedures;
    b) the AOC holder's operations specifications when applicable;
    c) the need for, and content of, the relevant parts of the AOC holder's operations manual when applicable;
  - 4.3. **knowledge of quality systems**;
  - 4.4. **five years relevant work experience** of which **at least two years should be from the aeronautical industry** in an appropriate position;

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Education

- 4.5. **a relevant engineering degree** or **an aircraft maintenance technician qualification with additional education** acceptable to the competent authority. ‘relevant engineering degree’ means an engineering degree from aeronautical, mechanical, electrical, electronic, avionic or other studies relevant to the maintenance and continuing airworthiness of aircraft/aircraft components;
- The above recommendation may be replaced by 5 years of experience additional to those already recommended by paragraph 4.4 above. These 5 years should cover an appropriate combination of experience in tasks related to aircraft maintenance and/or continuing airworthiness management and/or surveillance of such tasks;

Knowledge

- 4.6. thorough knowledge with the organisation's continuing airworthiness management exposition;
- 4.7. **knowledge of a relevant sample of the type(s) of aircraft** gained through a formalised training course. These courses should be at least at a level equivalent to Part-66 Appendix **III Level 1 General Familiarisation** and could be imparted by a Part-147 organisation, by the manufacturer, or by any other organisation accepted by the competent authority.
  ‘Relevant sample’ means that these courses should cover typical systems embodied in those aircraft being within the scope of approval.
- For all balloons and any other aircraft of 2 730 kg MTOM and below the formalised training courses may be replaced by demonstration of knowledge. This knowledge may be demonstrated by documented evidence or by an assessment performed by the competent authority. This assessment should be recorded.
- 4.8. knowledge **of maintenance methods.**
- 4.9. knowledge **of applicable regulations**

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End of presentation

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Auditing Techniques

Omer Pita and Salvador Alepuz
Airworthiness Experts

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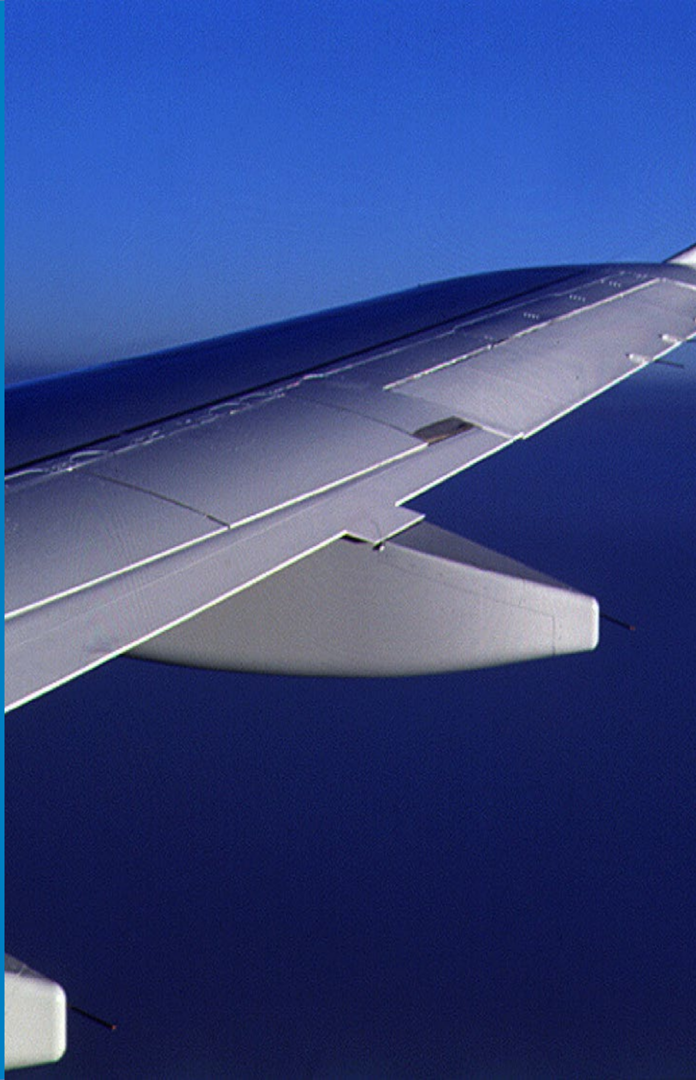
Auditor Competence Standards



Auditor’s Competence Standards

- What is competence? Three definitions (out of many):
  - A cluster of related abilities, commitments, knowledge, and skills that enable a person (or an organization) to act effectively in a job or situation. Competence indicates sufficiency of knowledge and skills that enable someone to act in a wide variety of situations.
    Because each level of responsibility has its own requirements, competence can occur in any period of a person's life or at any stage of his or her career.
  - The ability to do something well
  - Application of knowledge, skills, and behaviors in performance
    (ISO 10015 definition)

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Auditor's Competence Standards

- The four stages of competence (Noel Burch)
  - Unconscious incompetence
    The individual does not understand or know how to do something and does not necessarily recognize the deficit.
  - Conscious incompetence
    Though the individual does not understand or know how to do something, he or she does recognize the deficit, as well as the value of a new skill in addressing the deficit.
  - Conscious competence
    The individual understands or knows how to do something.
  - Unconscious competence
    The individual has had so much practice with a skill that it has become "second nature" and can be performed easily.

Auditor's Competence Standards

- Key elements of competence are:
  - Behavioral – based on personal values , belief and attitudes
  - Cognitive - knowledge
  - Functional - skill
- If any one element of competence is missing, competence is shifting to incompetence.
- Knowledge and skill are gained mostly through training and work experience.
- Human behaviors are partly innate (basic instincts, emotions, reflexes…) and partly learned through personal socializing experiences and training.

Auditor’s Competence Standards

- Confidence in the audit process and the ability to achieve its objectives depends on the competence of those individuals who are involved in planning and conducting audits, including auditors and audit team leaders.
- There should be auditor’s competence standard in place which should consider:
  - personal behavior and the ability to apply the knowledge and skills gained through education,
  - work experience,
  - auditor training and
  - audit experience.

Personal Behavior

- Auditors should possess the necessary qualities to enable them to act in accordance with the principles of auditing. Auditors should exhibit professional behavior during the performance of audit activities, including being:
  - ethical, i.e. fair, truthful, sincere, honest and discreet;
  - open-minded, i.e. willing to consider alternative ideas or points of view;
  - diplomatic, i.e. tactful in dealing with people;
  - observant, i.e. actively observing physical surroundings and activities;
  - perceptive, i.e. aware of and able to understand situations;
  - versatile, i.e. able to readily adapt to different situations;
  - tenacious, i.e. persistent and focused on achieving objectives;

Personal Behavior

- decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis;
- self-reliant, i.e. able to act independently whilst interacting effectively with others;
- acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
- open to improvement, i.e. to learn from situations, and striving for better audit results;
- culturally sensitive, i.e. observant and respectful to the culture of the auditee;
- collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel.

Knowledge and Skills

- Auditors should possess the knowledge and skills necessary to achieve the intended results of the audits they are expected to perform.
- All auditors should possess:
  - generic or common knowledge and skills and
  - discipline and sector-specific knowledge and skills.
- Audit team leaders should have the additional knowledge and skills necessary to provide leadership to the audit team.

Knowledge and Skills

- Generic or common knowledge and skills of the Auditor should cover:
  - Audit principles, procedures and methods,
  - Management system and reference documents,
  - Organizational context,
  - Applicable legal and contractual requirements and
  - Other requirements that apply to the auditee
- Sector-specific knowledge and skills of the Auditor are related to auditors specialization or trade that enables him to understand in detail particular type of management system and sector.
  - Examples: Auditor – pilot is required to understand the requirements and perform OPS audit, auditor – engineer….

Audit Team Knowledge and Skills

- Audit team member in auditing management systems addressing multiple disciplines should have the competence necessary to audit at least one of the management system disciplines and an understanding of the interaction and synergy between the different management systems.
- Audit team leaders conducting audits of management systems addressing multiple disciplines should understand the requirements of each of the management system standards and recognize the limits of their knowledge and skills in each of the disciplines.

Audit Team Knowledge and Skills

- Interdependence of Audit teams:
  - Each team member is able to cover one part of audit,
  - Whole team can cover the whole audit scope and
  - Lead Auditor is able to understand and manage all aspects of audit

Achieving of Auditor Competence

- Auditor knowledge and skills can be acquired using a combination of the following:
  - formal education/training and experience that contribute to the development of knowledge and skills in the management system discipline and sector the auditor intends to audit (professional training/experience)
  - training programs that cover generic auditor knowledge and skills;

Achieving of Auditor Competence (contd)

- experience in a relevant technical, managerial or professional position involving the exercise of judgement, decision making, problem solving and communication with managers, professionals, peers, customers and other interested parties;
- audit experience acquired under the supervision of an auditor in the same discipline.

→ Knowledge and experience standards should reflect the same

Audit Team Leaders

- → An audit team leader should have acquired additional audit experience to develop the knowledge and skills.
- → This additional experience should have been gained by working under the direction and guidance of a different audit team leader.

Evaluation of Auditors

- The Auditor criteria or competence standards should be:
  - qualitative (such as having demonstrated personal behavior, knowledge or the performance of the skills, in training or in the workplace) and
  - quantitative (such as the years of work experience and education, number of audits conducted, hours of audit training…).
- According to ISO 19011:2011, the evaluation should be conducted using two or more of the methods displayed on the next slide:

Evaluation of Auditors

Evaluation method	Objectives	Examples
Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and audit experience
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review
Interview	To evaluate personal behaviour and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews
Observation	To evaluate personal behaviour and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance
Testing	To evaluate personal behaviour and knowledge and skills and their application	Oral and written exams, psychometric testing
Post-audit review	To provide information on the auditor performance during the audit activities, identify strengths and weaknesses	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee.

Sample Auditor Competence Standard

Level	Position	Responsibilities and Authorities	Knowledge and experience
1	**Senior (Lead) Auditor**	- All authorizations as auditor(level 2) - Lead auditor in audit process	**Formal education:** - university degree (VI level) **specialized courses:** - all the requirements as for auditor (level 2) **experience:** - At least 20 audit days - To be a specialist (to have a scope) minimum 4 years in that particular area **evaluation:** - positively evaluated as Lead Auditor on behalf of QMS office by using form OB-QMS-010/Last revision
2	**Auditor**	- All authorizations as auditor observer - Participation in all audits as an auditor - Submitting reports about the area audited	**Formal education:** - secondary school (IV level) **specialized courses:** - all the requirements as for auditor observer **experience:** - At least 5 audit days as auditor observer - To be a specialist (to have scope) minimum 4 years in that particular area **evaluation:** - positively evaluated as Auditor on behalf of QMS office by using form OB-QMS-011/Last revision
3	**Auditor observer**	- Participates in audit preparation (check lists, organization, ...) - Participates in audit - Managing all audit documentation	**Formal education:** - secondary school (IV level) **specialized courses:** - quality briefing – quality management system or - internal auditor course **experience:** 6 months work experience
4	**Auditor Specialist**	- Participates in audits of specific areas (e.g. de/anti icing, DG, catering, fuel...) - Participates in audit preparation (check lists, organization, ...) - Managing all audit documentation - Audit performance alone allowed subject to qualification as LA. Otherwise, can only act as auditor within audit team.	**Formal education:** - secondary school (IV level) **specialized courses:** 1. quality briefing – quality management system or - internal auditor course 2. holder of specific certificate (De/Anti Icing, DG, HACCP, Fueling...) **experience:** 1 year experience in that particular area

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Maintaining and Improving Auditor Competence

- Auditors should maintain their auditing competence through regular participation in management system audits and continual professional development.
- This may be achieved through means such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities.
- Common practice to maintain Auditor’s knowledge and skills is that Auditors attend regular periodical refresher courses.
- The person managing the audit program should establish suitable mechanisms for the continual evaluation of the performance of the auditors, and audit team leaders.

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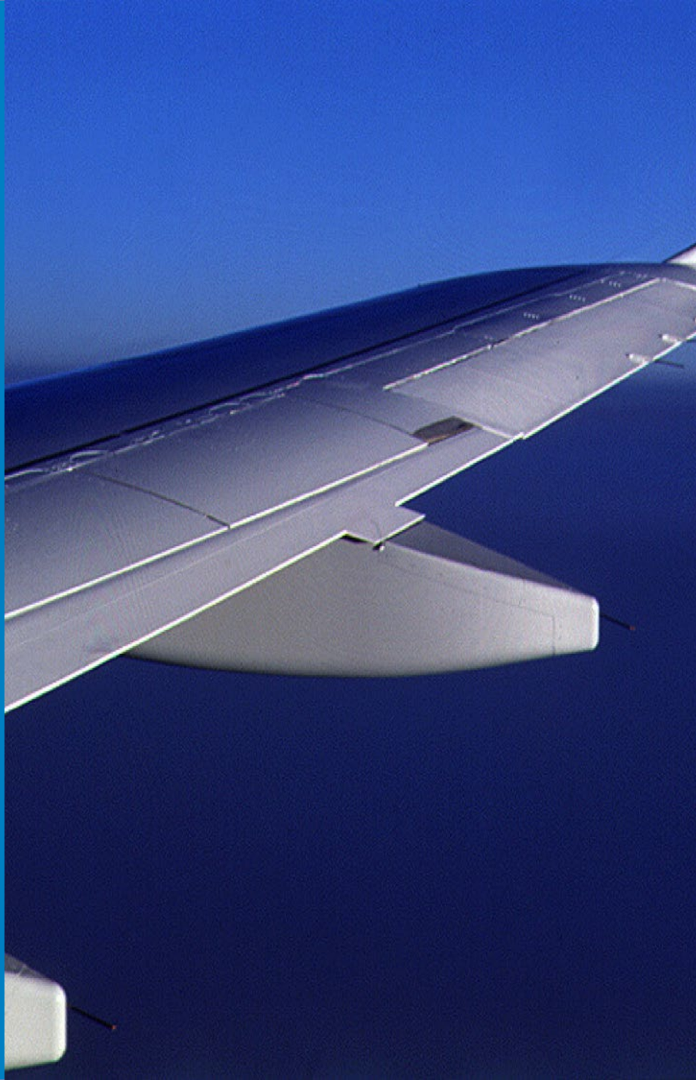
Communication during the Audit



Introduction

- The word “auditor” originates from the Latin word “audire”, meaning “to listen”.
- The auditor is a person who is good at listening to others in order to determine the facts.
- Consequently, developing good communication skills is essential prerequisite for becoming a good quality auditor.

Definition of Communication

→ Communication (from Latin *commūnicāre*, meaning "to share") is the act of conveying intended meanings from one entity or group to another through the use of mutually understood signs and semiotic rules.

Definition of Communication

- The basic steps of communication are:
  - The forming of communicative intent.
  - Message composition.
  - Message encoding and decoding.
  - Transmission of the encoded message as a sequence of signals using a specific channel or medium.
  - Reception of signals.
  - Reconstruction of the original message.
  - Interpretation and making sense of the reconstructed message.

Human Communication

- Humans use three different means of communication:
  - Nonverbal communication - the process of conveying meaning in the form of non-word messages.
    - Body language: facial expressions, gestures, body posture, eye movements and eye contact, touch, use of space
    - Universal signs and Culture specific signs
  - Verbal communication - the spoken conveying of message.
    Human language can be defined as a system of:
    - symbols (sometimes known as lexemes) and the
    - grammars (rules) by which the symbols are manipulated
  - Written communication - the message that is encoded and transmitted in written form

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Synchronous vs Asynchronous Communication

- Nonverbal and verbal communication are forms of synchronous communication.
  Synchronous communication is characterized by the fact that transmitting and receiving of the information happens at the same time.
- Written communication falls into category of asynchronous communication, where there is time delay between transmitting and receiving the information.

Synchronous vs Asynchronous Communication (contd)

- That substantial difference determines the use of different forms of communication:
  - For immediate real time transfer of complex information with feedback, synchronous communication is best suited.
  - For all information that needs to be preserved, used multiple times, or reviewed and analyzed, asynchronous communication is used

Verbal vs. Nonverbal Communication

- The verbal communication role would be to provide the raw, informative, specified and neutral data.
- The nonverbal communication would be used to add the "flavor" – to show attitude and emotion to the otherwise "dry" data.
- There is common misinterpretation of the fact that in human communication nonverbal part is predominant by 93% compared to 7% of verbal content of communication.

Verbal vs. Nonverbal Communication

- While that ratio might be true, true difference is in the fact that each of the two ways of communication is used for different purposes.
- Also it is important to know (especially for auditors) that most of time humans communicate on both nonverbal and verbal level simultaneously at the same time.

Importance of Written Communication

- Due to the nature of written communication, it is unavoidable in all situations where we:
  - Are not able to establish direct real time contact between communication subjects
  - We need to reuse, review or witness the information that has been transmitted
- Therefore, in audit process we can only rely on written documents when we want to objectively review or reconstruct historical events and information.

Active and Reflective Listening Techniques

- Active listening is a communication technique used in counseling, training and conflict resolution.
  It requires that the listener fully concentrate, understand, respond and then remember what is being said.

Active and Reflective Listening Techniques

- Reflective listening is a communication technique where the listener repeats back to the speaker what they have just heard to confirm understanding of both parties.
- Auditor should be active listener all the time, as long as he is sure that he is understanding the meaning and content of the transmitted information.
- When he is not sure that he has understood the meaning, he has to use reflective listening technique to verify that he has correctly understood meaning of the message.

Active Listening Technique

- To have a productive conversation or interview, it is important to establish atmosphere of cooperation and thrust.
- Active listening involves the auditor to observe the speaker's behavior and body language while carefully listening to the verbal part.
- Having the ability to interpret a person's body language lets the auditor develop a more accurate understanding of the speaker's message.

Active Listening Technique

- If message received is clearly pointing to an issue, the auditor may use reflective technique and paraphrase the speaker's words. This gives the speaker a chance to hear what he is speaking and to correct or rephrase his message if it was wrong.
- When auditor hasn’t understood the message, he asks additional questions to get enough information to understand. Reflective technique is then good to confirm final understanding.

Active Listening Technique (cont'd)

- Talk as little as possible, let the other person talk.
- Accept silence for a while
- Many people are afraid of silence, but it can be useful (we have time to think what to say next and the other person has time to say what they have to say)

Active Listening Technique (cont'd)

- → Try not to interrupt the speaker, unless he is clearly missing the subject of the conversation
- → Do not jump to conclusions or make judgements that lead the speaker
- → Do not ask questions that suggest the answers
- → Do not explain what the speaker meant to say, ask speaker and he should explain if necessary

Example of Questions to Ask

- Questions asked should preferably be of open type:
  - How do you implement this instruction?
  - To what should you pay attention?
  - Do you record these activities? How?
  - What is the purpose of this instruction?
  - What happens in case this instruction is not followed?
  - Can you prove the efficiency of this measure?
  - Have any errors occurred? Which ones? Is there a list of errors? Where is it?

Other Means of Nonverbal Communication

Which one is auditor?

Our apearance is very important: clothes , jewlery, gadgets, hairstyle.....

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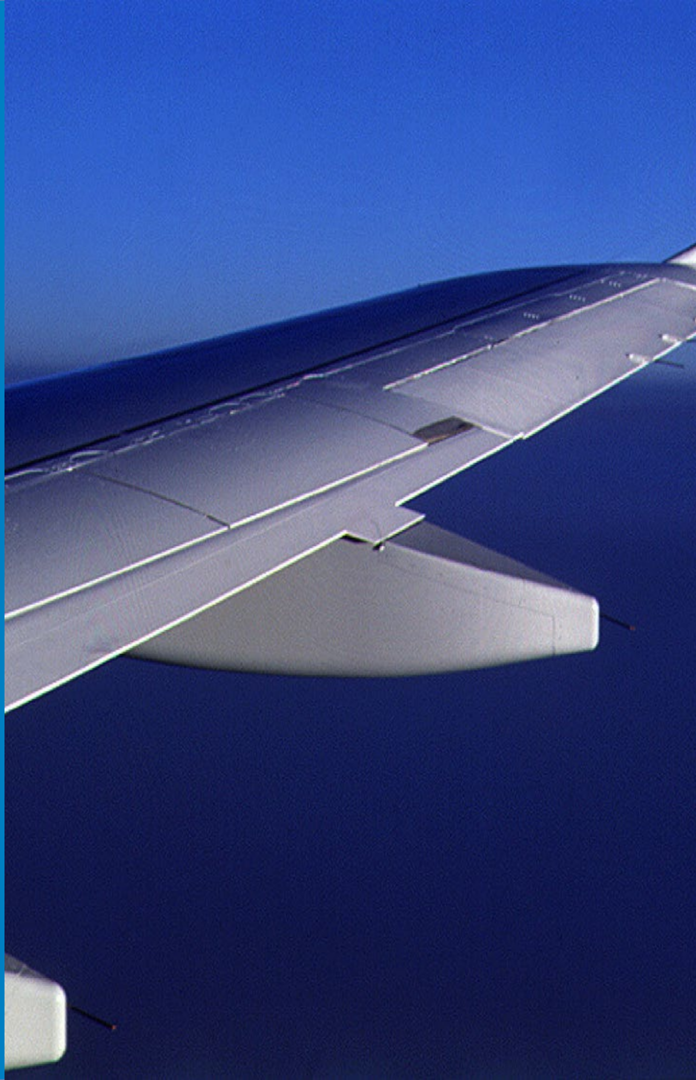
Auditor’s Behavior



Introduction

→ Two Biggest Lies in the Aviation:

Conversation during the audit in cockpit:

Auditor: „*Hello, I am here to help you!*”

Captain: „Good day to you sir! *We're glad to have you here.*”

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Introduction

- Bearing in mind primary purpose of audit, it is fully understandable that audit can be highly stressful activity for all involved.
- The success of the audit highly depends on proper behavior of auditor
- Behavior of auditor should be based on six principles: integrity, fair presentation, due professional care, confidentiality, evidence based approach and independence.

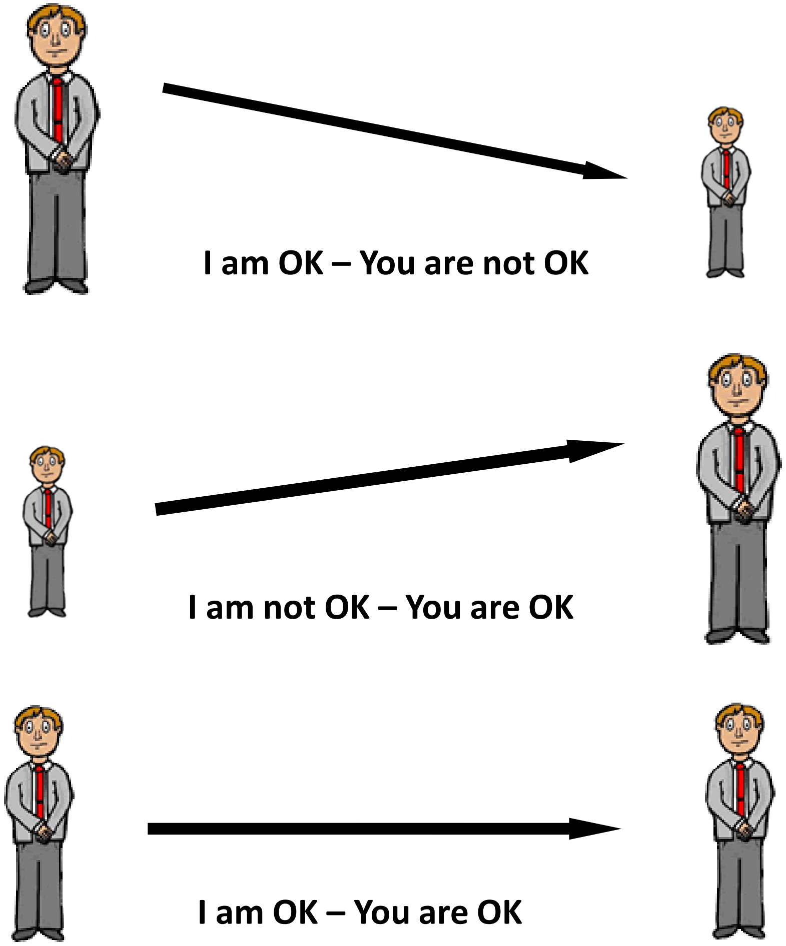
Personal Behavior

- Auditors should exhibit professional behavior during the performance of audit activities, including being:
  - ethical, i.e. fair, truthful, sincere, honest and discreet;
  - open-minded, i.e. willing to consider alternative ideas or points of view;
  - diplomatic, i.e. tactful in dealing with people;
  - observant, i.e. actively observing physical surroundings and activities;
  - perceptive, i.e. aware of and able to understand situations;
  - versatile, i.e. able to readily adapt to different situations;
  - tenacious, i.e. persistent and focused on achieving objectives;
  - decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis;

Personal Behavior (cont'd)

- self-reliant, i.e. able to act independently whilst interacting effectively with others;
- acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
- open to improvement, i.e. to learn from situations, and striving for better audit results;
- culturally sensitive, i.e. observant and respectful to the culture of the auditee;
- collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel.

Right Attitude



Mind Your Manners

- → Maintain a pleasant atmosphere
- → Do not change subjects of conversation, „ deal with one thing at a time".
- → Do not make statements relating to the other person or other people, do not judge the people!
- → Be moderate when giving both positive and negative feedback during evaluation, don't get too enthusiastic or too depressing!
- → Continuously pay attention to your body language, composure, tone of voice and relationship towards the audited person!
- → Show your appreciation and respect, „thank you" is a good word.

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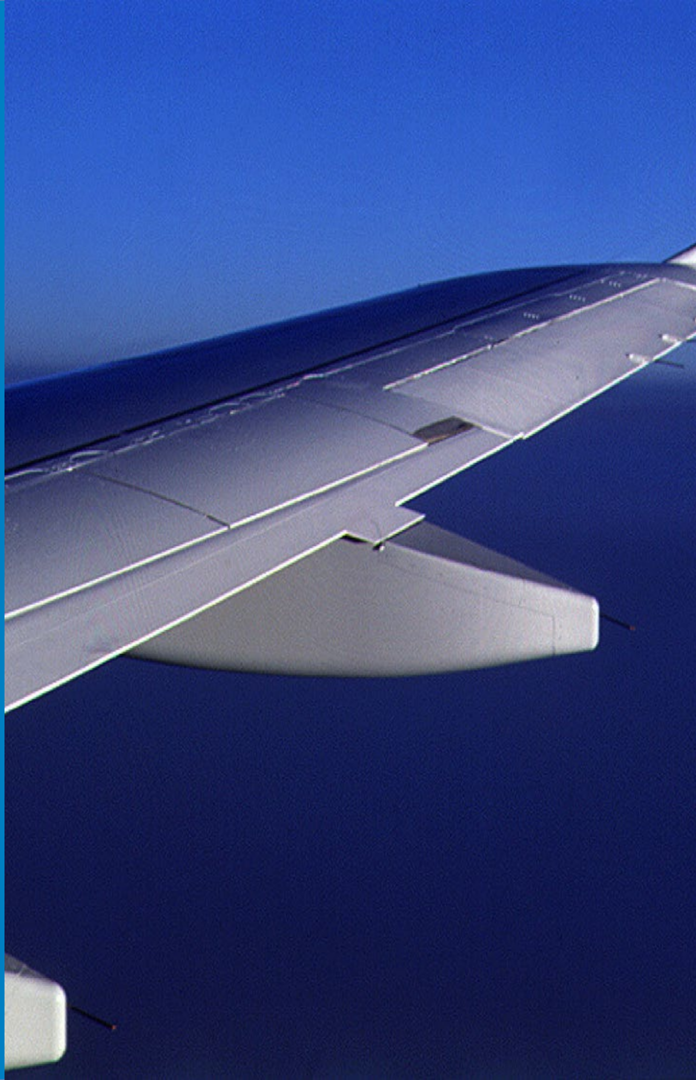
Auditing Methods



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Applying Auditing Methods (ISO 19011:2011)

Extent of involvement between the auditor and the auditee	Location of the auditor	
	On-site	**Remote**
Human interaction	Conducting interviews. Completing checklists and questionnaires with auditee participation. Conducting document review with auditee participation. Sampling.	Via interactive communication means: — conducting interviews; — completing checklists and questionnaires; — conducting document review with auditee participation.
No human interaction	Conducting document review (e.g. records, data analysis). Observation of work performed. Conducting on-site visit. Completing checklists. Sampling (e.g. products).	Conducting document review (e.g. records, data analysis). Observing work performed via surveillance means, considering social and legal requirements. Analysing data.
On-site audit activities are performed at the location of the auditee. Remote audit activities are performed at any place other than the location of the auditee, regardless of the distance. Interactive audit activities involve interaction between the auditee's personnel and the audit team. Non-interactive audit activities involve no human interaction with persons representing the auditee but do involve interaction with equipment, facilities and documentation.		

Conducting a Document Review

- →The auditors should consider if:
  - → the information in the documents provided is:
    - →complete (all expected content is contained in the document);
    - →correct (the content conforms to other reliable sources such as standards and regulations);
    - →consistent (the document is consistent in itself and with related documents);
    - →current (the content is up to date);
  - → the documents being reviewed cover the audit scope and provide sufficient information to support the audit objectives;

Conducting a Document Review

- The use of information and communication technologies, depending on the audit methods, promotes efficient conduct of the audit.
- Specific care is needed for information security.

Sampling

- Audit sampling takes place when it is not practical or cost effective to examine all available information during an audit, e.g. records are too numerous or too dispersed geographically to justify the examination of every item in the population.
- Audit sampling of a large population is the process of selecting less than 100 % of the items within the total available data set (population) to obtain and evaluate evidence in order to form a conclusion concerning the population.
- The risk associated with sampling is that the samples **may be not representative** of the population from which they are selected, and thus the auditor's conclusion may be wrong.

Sampling Procedure

- Audit sampling typically involves the following steps:
  - establishing the objectives of the sampling plan;
  - selecting the extent and composition of the population to be sampled;
  - selecting a sampling method;
  - determining the sample size to be taken;
  - conducting the sampling activity;
  - compiling, evaluating, reporting and documenting results.

Sampling Methods

- Audits can use either:
  - judgement-based sampling or
  - statistical sampling
- Judgement-based sampling relies on the knowledge, skills and experience of the audit team

Sampling Methods

- A drawback to judgement-based sampling is that there can be no statistical estimate of the effect of uncertainty in the findings of the audit and the conclusions reached.
- Nevertheless, in aviation quality audits, judgment based sampling is the most frequently used sampling method with usual application of progressive increase of sample in case of findings in small sample.

Judgment Based Sampling

- Judgment based sampling method uses judgment of auditor to determine sample size that will be inspected.
- For judgement-based sampling, the following can be considered:
  - previous audit experience within the audit scope;
  - complexity of requirements (including legal requirements) to achieve the objectives of the audit;
  - complexity and interaction of the organization’s processes and management system elements;
  - degree of change in technology, human factor or management system;
  - previously identified key risk areas and areas of improvement;
  - output from monitoring of management systems.

Statistical Sampling

- Statistical sampling design uses a sample selection process based on probability theory.
  - Attribute-based sampling is used when there are only two possible sample outcomes for each sample (e.g. correct/incorrect or pass/fail).
  - Variable-based sampling is used when the sample outcomes occur in a continuous range.

Statistical Sampling

- The sampling plan should take into account whether the outcomes being examined are likely to be attribute-based or variable-based.
  - For example, when evaluating conformance of completed forms to the requirements set out in a procedure, an attribute-based approach could be used.
  - When examining the occurrence of food safety incidents or the number of security breaches, a variable-based approach would likely be more appropriate.

Statistical Sampling (cont'd)

- When a statistical sampling plan is developed, the level of sampling risk that the auditor is willing to accept is an important consideration. This is often referred to as the **acceptable confidence level**.
  - For example, a sampling risk of 5 % corresponds to an acceptable confidence level of 95 %.
  - A sampling risk of 5 % means the auditor is willing to accept the risk that 5 out of 100 (or 1 in 20) of the samples examined will not reflect the actual values that would be seen if the entire population was examined.

Statistical Sampling (cont'd)

- When statistical sampling is used, auditors should appropriately document the work performed. This should include a description of the population that was intended to be sampled, the sampling criteria used for the evaluation, the statistical parameters and methods that were utilized, the number of samples evaluated and the results obtained.

ISO 2859-1 Acceptable Quality Level – Statistical Sampling Method

Lot size		Special inspection level				General inspection levels		
		S-1	S-2	S-3	S-4	I	II	III
2 to	8	A	A	A	A	A	A	B
9 to	15	A	A	A	A	A	B	C
16 to	25	A	A	B	B	B	C	D
26 to	50	A	B	B	C	C	D	E
51 to	90	B	B	C	C	C	E	F
91 to	150	B	B	C	D	D	F	G
151 to	280	B	C	D	E	E	G	H
281 to	500	B	C	D	E	F	H	J
501 to	1 200	C	C	E	F	G	J	K
1201 to	3 200	C	D	E	G	H	K	L
3201 to	10 000	C	D	F	G	J	L	M
10 001 to	35 000	C	D	F	H	K	M	N
35 001 to	150 000	D	E	G	J	L	N	P
150 001 to	500 000	D	E	G	J	M	P	Q
500 001 and over		D	E	H	K	N	Q	R

AQL – The Inspection Levels

- Three general and four special inspection levels are commonly used.
- The general inspection levels (1 to 3) are typically used for non-destructive inspection.
  - Level 2 is considered the norm (except for small sample sizes).
  - Level 1 requires only 40 percent of inspection level 2 and can be used where less discrimination is needed.
  - Level 3 equals 160 percent of the amount of inspection level 2. Level 3 will give a lower risk of accepting a lot with excessive number of defects. However, inspection of a larger number of samples is required.

EASA

AQL – The Inspection Levels

- Special Levels S-1, S-2, S-3 and S-4 may be used where relatively small sample sizes are necessary or large sampling risks can be taken.
  - Examples of this are inspections involving destructive or costly (time consuming) type inspections where large lots are involved, small sample sizes desired, and large risks can be tolerated such as repetitive processes (screw machine, stamping, bolting operation, etc.) performed by a quality supplier. Larger sample sizes are required for inspection levels increasing from S1 to S4.

AQL – Sampling Plan

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																									
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑
D	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑
E	13	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	↑	↑	↑
F	20	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑
G	32	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑
H	50	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑
J	80	↓	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑
K	125	↓	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
L	200	↓	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
M	315	↓	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
N	500	↓	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
P	800	↓	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Q	1 250	0 1	↑	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
R	2 000	↑	↑	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

Example of using AQL

- Lot size = 50 000 items, non critical
- We need AQL = 1,5% (meaning max 1,5 defective items per 100 items)
- Question: what is necessary sample size, and what is acceptable number of defective items in the sample?
- Step 1: Determine Inspection Level and Code Letter (see Table 1):
  - Since item is non critical, it is appropriate to select General Inspection Level I, which returns Code Letter L for lot of 50 000.
- Step 2: Determine Sample size and max acceptable number of defective items (see Table 2):
  - Code Letter indicates Sample Size of 200, and AQL 1,5 (column) indicates max acceptable 7 defective items (8 and more are rejectable)

Conducting interviews

- Interviews are one of the important means of collecting information and should be carried out in a manner adapted to the situation and the person interviewed, either face to face or via other means of communication.
- However, the auditor should consider the following:
  - interviews should be held with persons from appropriate levels and functions performing activities or tasks within the audit scope;
  - interviews should normally be conducted during normal working hours and, where practical, at the normal workplace of the person being interviewed;
  - attempt to put the person being interviewed at ease prior to and during the interview;

Conducting interview (cont’d)

- the reason for the interview and any note taking should be explained;
- interviews may be initiated by asking the persons to describe their work;
- careful selection of the type of question used (e.g. open, closed, leading questions);
- the results from the interview should be summarized and reviewed with the interviewed person;
- the interviewed persons should be thanked for their participation and cooperation.

Audit Findings

- Determining audit findings
  - When determining audit findings (positive or negative), the following should be considered:
    - follow-up of previous audit records and conclusions – verify that corrective actions taken were effective;
    - sample size – before raising finding make sure that sample which has been determined is adequate to give confidence to auditor’s decision;
    - categorization of the audit findings – in aviation, findings have to be categorized, categorization has to be based on clear rationale and basic risk assesment;

Audit Findings

- Recording conformities (not usual in aviation quality audits)
  - For records of conformity, the following should be considered:
    - identification of the audit criteria – requirement against which conformity is shown;
    - audit evidence to support conformity;
    - description of conformity or declaration of conformity, if applicable.

Audit Findings

- Recording nonconformities
  - For records of nonconformity, the following should be considered:
    - reference to audit criteria - requirement;
    - description of nonconformity or nonconformity declaration, be careful not to impose corrective action in finding description;
    - audit evidence – should clearly point to non-conformance;
    - related audit findings, if applicable – findings can be clustered in a way that one finding triggers another in a cascade way. Auditor should consider what layout of findings would best serve corrective action process and follow up activities.

Audit Findings

- Dealing with findings related to multiple requirements
  - Depending on the what is convenient to the auditee, the auditor may raise either:
    - separate findings for each requirement; or preferably
    - a single finding, combining the references to multiple requirements.

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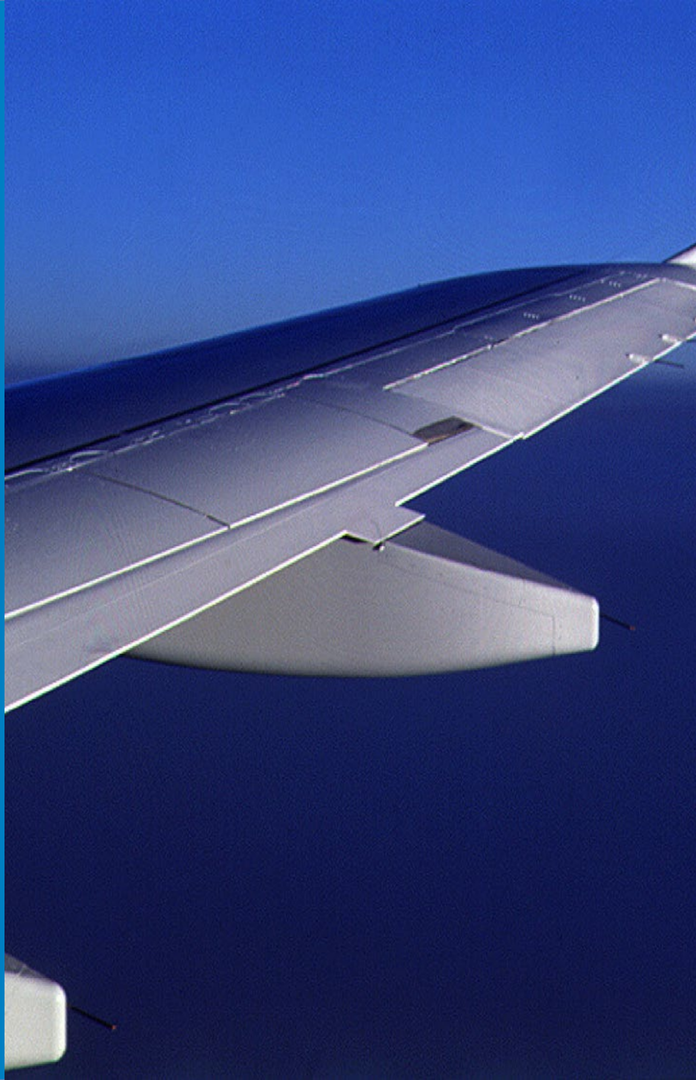
Performance of Audits

An Agency of the European Union



Types of Audits

- System audits examine:
  - The compliance and adequacy of organizational quality documents
  - Compliance of management system, organization and organizational procedures with applicable requirements and internal standards
- Process audits examine:
  - Compliance of the process performance with standards set and
  - Adequacy of procedures and compliance with applicable procedures in every process step
  - Overall control over process, process inputs and outputs
- Product / service audits examine:
  - compliance of product or service with applicable requirements

Initiating the Audit

- Quality Audit is normally initiated by Quality Manager in accordance with Audit Program
- Audit Order is standard document that initiates an audit.
- When an audit is initiated, the responsibility for conducting the audit remains with the assigned audit team leader until the audit is completed.

Establishing Initial Contact with the Auditee

- The initial contact with the auditee for the performance of the audit can be informal or formal and should be made by the audit team leader. The main goals of the initial contact are the following:
  - establish communication with the auditee;
  - provide information on the audit objectives, scope, methods and audit team composition, including technical experts;
  - request access to relevant documents and records for planning purposes;
  - make arrangements for the audit including scheduling the dates;
  - determine any location-specific requirements for access, security, health and safety or other;
  - agree on the attendance of observers and the need for guides for the audit team;
  - determine any areas of interest or concern to the auditee in relation to the specific audit.

Determining the Feasibility of the Audit

- The feasibility of the audit should be determined to provide reasonable confidence that the audit objectives can be achieved.
- The determination of feasibility should take into consideration such factors as the availability of the following:
  - sufficient and appropriate information for planning and conducting the audit;
  - adequate auditee’s resources available for cooperation;
  - adequate time and resources for conducting the audit.
- Where the audit is not feasible, an alternative should be proposed to the audit client, in agreement with the auditee.

Performing Document Review in Preparation for the Audit

- The relevant management system documentation of the auditee should be reviewed in order to:
  - Verify compliance of system documentation with applicable requirements
  - Gather information to prepare audit activities and applicable audit work documents , e.g. check lists on processes, functions;
  - establish an overview of the extent of the system documentation to detect possible gaps.
- The documentation should include, as applicable, management system documents and records, as well as previous audit reports.
- The document review should take into account the size, nature and complexity of the auditee's management system and organization, and the audit objectives and scope.

Preparing the Audit Plan

- The audit plan should consider the effect of the audit activities on the auditee’s processes and provide the basis for the agreement regarding the conduct of the audit.
- The plan should facilitate the efficient scheduling and coordination of the audit activities in order to achieve the objectives effectively.
- In preparing the audit plan, the audit team leader should be aware of the following:
  - the composition of the audit team and its collective competence;
  - The scope that has to be covered, audit locations and complexity of organization and processes
  - the risks to the organization created by the audit.

Audit Plan Contents

→ The audit plan should cover or reference the following:

a) the audit objectives;

b) the audit scope, including identification of the organizational and functional units, as well as processes to be audited;

c) the audit criteria and any reference documents;

d) the locations, dates, expected time and duration of audit activities to be conducted, including meetings with the auditee's management;

e) the audit methods to be used, including the extent to which audit sampling is needed to obtain sufficient audit evidence and the design of the sampling plan, if applicable;

f) the roles and responsibilities of the audit team members, as well as guides for observers;

g) the allocation of appropriate resources to critical areas of the audit.

Assigning Work to the Audit Team

- The audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific processes, activities, functions or locations.
- Such assignments should take into account the independence and competence of auditors and the effective use of resources, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts.
- Audit team briefings should be held, as appropriate, by the audit team leader in order to allocate work assignments and decide possible changes.
- Changes to the work assignments can be made as the audit progresses in order to ensure the achievement of the audit objectives.

Preparing Work Documents

- The audit team members should collect and review the information relevant to their audit assignments and prepare work documents, as necessary, for reference and for recording audit evidence. Such work documents may include the following:
  - checklists;
  - audit sampling plans;
  - forms for recording information, such as supporting evidence, audit findings and records of meetings.
- The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit.

Conducting the Opening Meeting

- The purpose of the opening meeting is to:
  - confirm the agreement of all parties (e.g. auditee, audit team) to the audit plan;
  - introduce the audit team;
  - ensure that all planned audit activities can be performed.
- An opening meeting should be held with the auditee's management and, where appropriate, those responsible for the functions or processes to be audited. During the meeting, an opportunity to ask questions should be provided.
- The degree of detail should be consistent with the familiarity of the auditee with the audit process. In many instances, e.g. internal audits in a small organization, the opening meeting may simply consist of communicating that an audit is being conducted and explaining the nature of the audit.

Items for Discussion on Opening Meeting

- For some audit situations, the meeting may be formal and records of attendance should be kept.
- The meeting should be chaired **by the audit team leader**, and the following items should be considered, as appropriate:
  - introduction of the participants, including observers and guides, and an outline of their roles;
  - confirmation of the audit objectives, scope and criteria;
  - confirmation of the audit plan and other relevant arrangements with the auditee, such as the date and time for the closing meeting, any interim meetings between the audit team and the auditee's management, and any late changes;
  - presentation of the methods to be used to conduct the audit, including advising the auditee that the audit evidence will be based on a sample of the information available;

Items for Discussion on Opening Meeting (cont'd)

- introduction of the methods to manage risks to the organization which may result from the presence of the audit team members;
- confirmation of formal communication channels between the audit team and the auditee; confirmation of the language to be used during the audit;
- confirmation that, during the audit, the auditee will be kept informed of audit progress;
- confirmation that the resources and facilities needed by the audit team are available;
- confirmation of matters relating to confidentiality and information security;
- confirmation of relevant health and safety, emergency and security procedures for the audit team;

Items for Discussion on Opening Meeting (cont’d

- information on the method of reporting audit findings including grading, if any;
- information about conditions under which the audit may be terminated;
- information about the closing meeting;
- information about how to deal with possible findings during the audit;
- information about any system for feedback from the auditee on the findings or conclusions of the audit,
- including complaints or appeals.

Performing Document Review while Conducting the Audit

- The auditee's relevant documentation should be reviewed to:
  - determine the conformity of the system, as far as documented, with audit criteria;
  - gather information to support the audit activities.
- The review may be combined with the other audit activities and may continue throughout the audit, providing this is not detrimental to the effectiveness of the conduct of the audit.
- If adequate documentation cannot be provided within the time frame given in the audit plan, the audit team leader should inform both the person managing the audit program and the auditee. Depending on the audit objectives and scope, a decision should be made as to whether the audit should be continued or suspended until documentation concerns are resolved.

Communicating During the Audit

- During the audit, it may be necessary to make formal arrangements for communication within the audit team, as well as with the auditee, the audit client and potentially with external bodies (e.g. regulators), especially where legal requirements require the mandatory reporting of non-compliances.
- The audit team should confer periodically to exchange information, assess audit progress, and reassign work between the audit team members, as needed.
- During the audit, the audit team leader should periodically communicate the progress of the audit and any concerns to the auditee and audit client, as appropriate. Evidence collected during the audit that suggests an immediate and significant risk to the auditee should be reported without delay to the auditee and, as appropriate, to the management.

Communicating During the Audit

- Any concern about an issue outside the audit scope should be noted and reported to the audit team leader, for possible communication to the audit client and auditee.
- Where the available audit evidence indicates that the audit objectives are unattainable, the audit team leader should report the reasons to the auditee to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit.
- Any need for changes to the audit plan which may become apparent as auditing activities progress should be reviewed and approved, as appropriate, by both the person managing the audit program and the auditee.

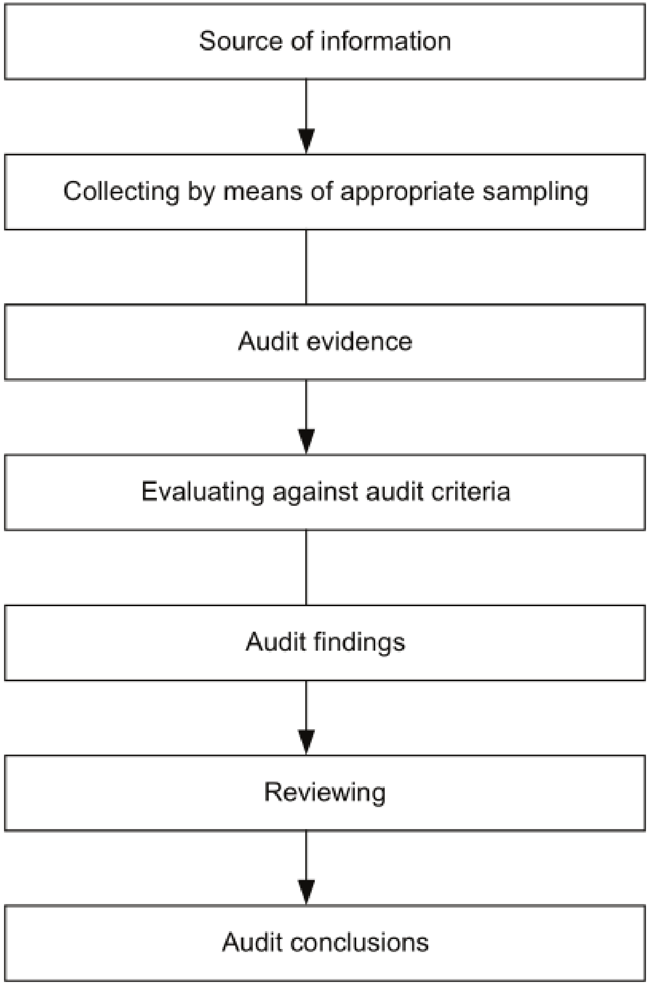
Roles and Responsibilities of Guides and Observers

- Guides and observers (e.g. regulator or other interested parties) may accompany the audit team.
- They should not influence or interfere with the conduct of the audit.
- If this cannot be assured, the audit team leader should have the right to deny observers from taking part in certain audit activities.

Roles and Responsibilities of Guides

- Guides, appointed by the auditee, should assist the audit team and act on the request of the audit team leader.
- Their responsibilities should include the following:
  - a) assisting the auditors in identifying individuals to participate in interviews and confirming timings;
  - b) arranging access to specific locations of the auditee;
  - c) ensuring that rules concerning location safety and security procedures are known and respected by the audit team members and observers.
- The role of the guide may also include the following:
  - witnessing the audit on behalf of the auditee;
  - providing clarification or assisting in collecting information.

Collecting and Verifying Information



Generating audit findings

- Audit evidence should be evaluated against the audit criteria in order to determine audit findings.
- Audit findings can indicate conformity or nonconformity with audit criteria. When specified by the audit plan, individual audit findings should include conformity and good practices along with their supporting evidence, opportunities for improvement, and any recommendations to the auditee.

Generating audit findings

- Nonconformities and their supporting audit evidence should be recorded. Nonconformities should be graded.
- They should be reviewed with the auditee in order to obtain acknowledgement that the audit evidence is accurate, and that the nonconformities are understood. Every attempt should be made to resolve any diverging opinions concerning the audit evidence or findings, and unresolved points should be recorded.
- The audit team should meet as needed to review the audit findings at appropriate stages during the audit.

Preparing Audit Conclusions

- The audit team should confer prior to the closing meeting in order to:
  - review the audit findings, and any other appropriate information collected during the audit, against the audit objectives;
  - agree on the audit conclusions, taking into account the uncertainty inherent in the audit process;
  - prepare recommendations, if specified by the audit plan;
  - discuss audit follow-up, as applicable.

Conducting the Closing Meeting

- A closing meeting, facilitated by the audit team leader, should be held to present the audit findings and conclusions. Participants in the closing meeting should include the management of the auditee and, where appropriate, those responsible for the functions or processes which have been audited.
- If applicable, the audit team leader should advise the auditee of situations encountered during the audit that may decrease the confidence that can be placed in the audit conclusions.
- If defined in the management system or by agreement with the audit client, the participants should agree on the time frame for an action plan to address audit findings.

Conducting the Closing Meeting

- As appropriate, the following should be explained to the auditee in the closing meeting:
  - advising that the audit evidence collected was based on a sample of the information available;
  - the method of reporting;
  - the process of handling of audit findings and possible consequences;
  - presentation of the audit findings and conclusions in such a manner that they are understood and acknowledged by the auditee’s management;
  - any related post-audit activities (e.g. implementation of corrective actions, audit complaint handling, appeal process).
- Any diverging opinions regarding the audit findings or conclusions between the audit team and the auditee should be discussed and, if possible, resolved. If not resolved, this should be recorded.

Audit Report

AUDIT REPORT

QUALITY DEPARTMENT

AUDIT ORDER No:	18/2016
AUDIT DATES:	17. - 19.11.2016
AUDITEE:	AMC-Engineering department
RESPONSIBLE MANAGER:	Daniel Fong
AUDITED PERSONS:	Didier Bousquet, Stephen Martin, Ivana Horvat
AUDIT TEAM:	
Lead auditor:	Omer Pita
Auditor:	Denis Budimir, Daniela Mayer
Expert:	Mehmed Hasanović
Observer:	

INTRODUCTION

Here is the place for general description of the audit event, how was the audit carried out, level of communication and cooperation with auditee, positive findings or strong points of auditee discovered during the audit.

LIST OF NON-COMPLIANCES

No.	Reference:	Non-Compliance	Level
1.	Regulation requirement or internal standard reference	Description of finding	
2.			
3.			

RECOMMENDATIONS AND CONCLUSION

Recommendations for the overall improvement of Audit process and/or
any additional information that Audit Team needs to communicate in relation to particular audit.

Developed by	Name and Surname	Date:	Signature:
Audit Team Leader	Omer Pita	20.11.2016	
Auditor:	Denis Budimir	20.11.2016	
Auditor:	Daniela Mayer	20.11.2016	
Auditor:			
Expert:	Mehmed Hasanović	20.11.2016	
Quality Manager Endorsement:			

Distributed to:	Responsible Manager		
	Sector Director		

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End of presentation

Thank you for your attention!

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EASA Part M and CAME

Omer Pita and Salvador Alepuz
Airworthiness Experts

European Union Aviation Safety Agency

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European Aviation Safety Agency EASA

- The European Aviation Safety Agency (EASA) is
  an agency of the European Union (EU) with
  regulatory and executive tasks in the field of civil aviation safety.
- It is based in Cologne, Germany.
- The EASA was created on 15 July 2003 and it reached full functionality in 2008, taking over functions of the former Joint Aviation Authorities (JAA).
- The legal position of EASA is unique due to the fact that EASA is rulemaker for EU and also does product certification (TC) for all EU members, but is not national authority and therefore is not represented as member state in ICAO.
- National authorities of EU member states have partial certification (no TC) function and oversight function within their countries.

EASA (cont'd)

- EASA carries out audits of the EU Member States NAA under standardization program with aim to standardize EU NAA certification and oversight standards.
- EASA also launched quite successful SAFA (Safety Assessment of Foreign Aircraft) inspection program which is gaining popularity worldwide, as more and more countries join the program.
- Internationally, EASA regulations are increasingly taken as raw model for national aviation regulations by many non-EU states.

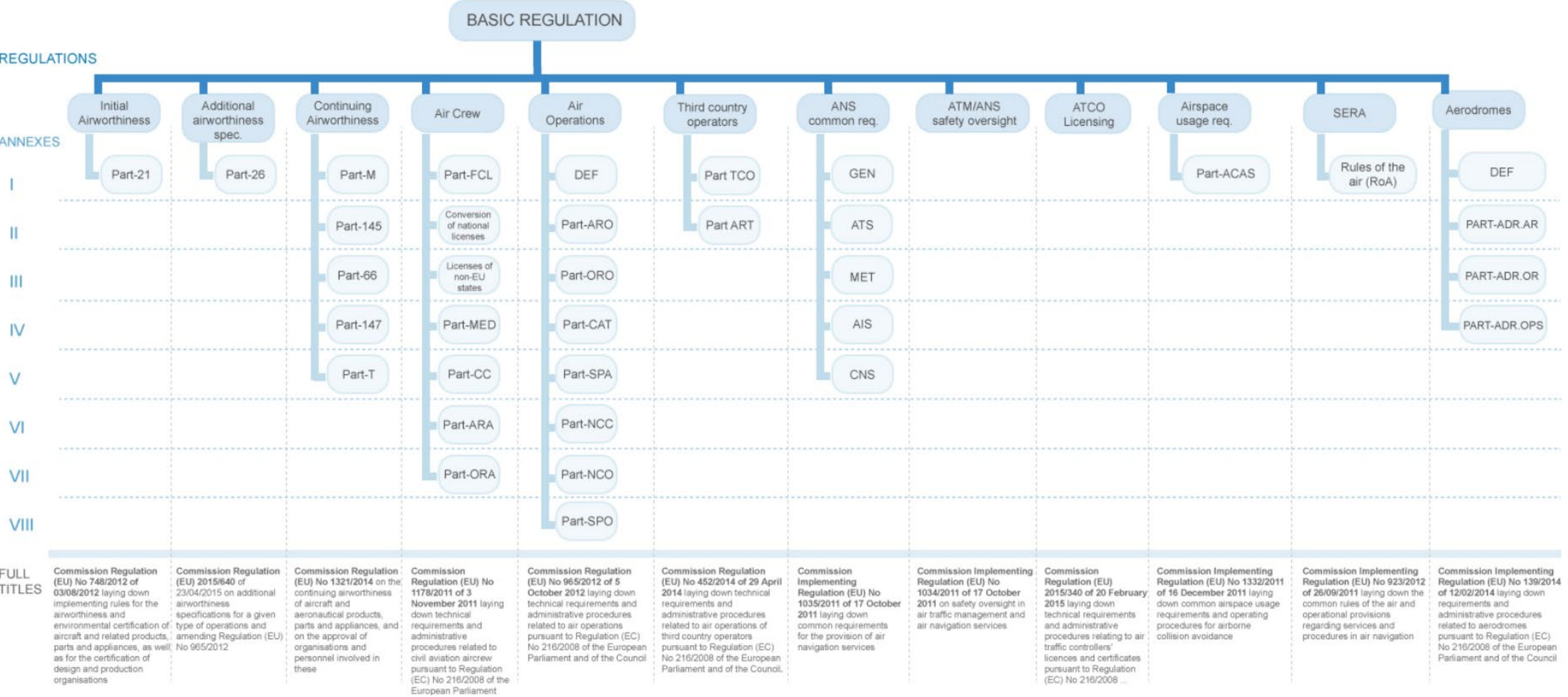
About Rulemaking Procedure in EU

- EASA – the European Aviation Safety Agency using NPA (Notice of Proposed Amendment) process creates a draft to a legislation which is intended to be applied throughout the European Member States
- The European Commission releases the work of the Agency in the form of a Commission Regulation or Directive, by means of which the contents of that work actually become binding law within the European Union
  - Commission Regulation applies directly within EU
  - Commission Directive gives essential content of regulation which has to be regulated by each Member State in national regulations (indirect application)

About Rulemaking Procedure in EU

- The Member States, if necessary, must adjust their national regulations to allow for direct implementation of the Commission Regulation or, in case of Commission Directive, Member States have to enact national regulation to implement the Directive.
- EASA creates and enacts „soft law” based on above EU Regulations in form of AMC (Acceptable Means of Compliance), GM (Guidance Material) and CS (Certification Specifications).

Structure of EU (EASA) Regulations



Structure of EU (EASA) Regulations

„Hard law" – Commission Regulation

Air Operations

Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council.

Show regulations

Acceptable Means of Compliance and Guidance Material

GM to the Cover Regulation	DEF	Part-ARO
Part-ORO	Part-CAT	Part-SPA
Part-NCC	Part-NCO	Part-SPO

Certification Specification

CS-FSTD(A)	CS-FSTD(H)	CS-FTL.1

„Soft law" – GM, AMC and CS

DEF= Definitions; ARO=Authority Requirements; ORO=Organizational Requirements; CAT=Commercial Transport Requirements; SPA=Special Performance Approvals; NCC=Non-commercial, complex aircraft; NCO=Non-commercial, non-complex aircraft; SPO=Special Operations (like aerial work)

Structure of EU (EASA) Regulations

„Hard law" – Commission Regulation

Continuing Airworthiness

Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks

Show regulations

Easy Access Rules: Continuing Airworthiness (Regulation (EU) No 1321/2014)

Acceptable Means of Compliance and Guidance Material

Part-M	Part-145	Part-66
Part-147	Part-T	

„Soft law" – GM, AMC and CS

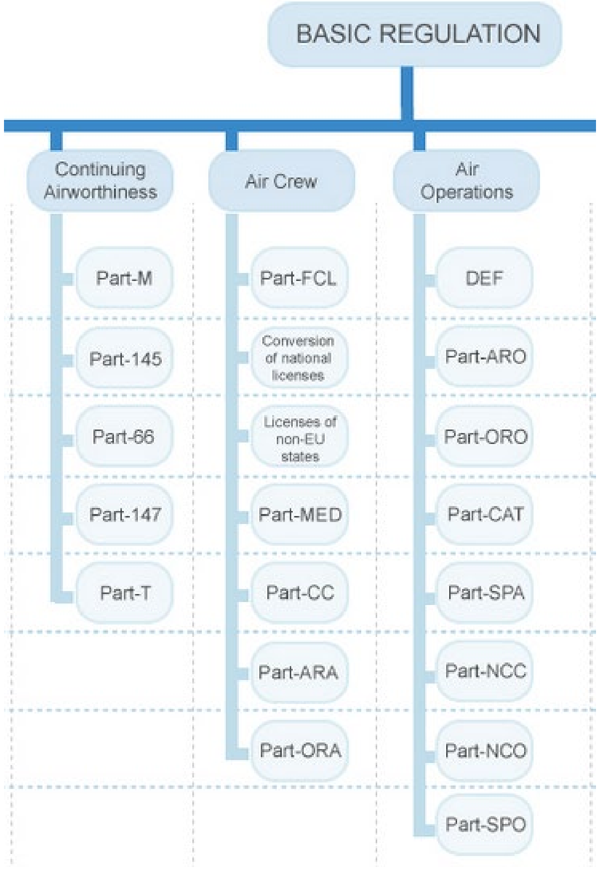
EASA AMC, GM & CS

- Even though it is a „soft law”, meaning it is not obligatory, in EU is compliance with AMC, GM and CS considered to be mandatory, unless applicant for certificate is not ready to develop and „defend” Alternative Means of Compliance which he has to present to certifying Authority.
- All major EU aviation safety regulations can be downloaded in consolidated form from EASA website: (*https://www.easa.europa.eu/document-library/technical-publications*)

Core EU Regulations for Airline Operations and Maintenance

→ Example of regulations applicability:

- Airlines (commercial air transport):
  - Basic Regulation
  - Air Operations Regulation
  - Part-CAT (requirements for commercial operations)
  - Part-ORO (organisational requirements)
  - Part-SPA (specific approvals - PBN, RVSM, MNPS, LVO…)
- Airlines CAMO & standalone CAMO organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-M
- Maintenance organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-145
- Maintenance training organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-147
  - Part-66



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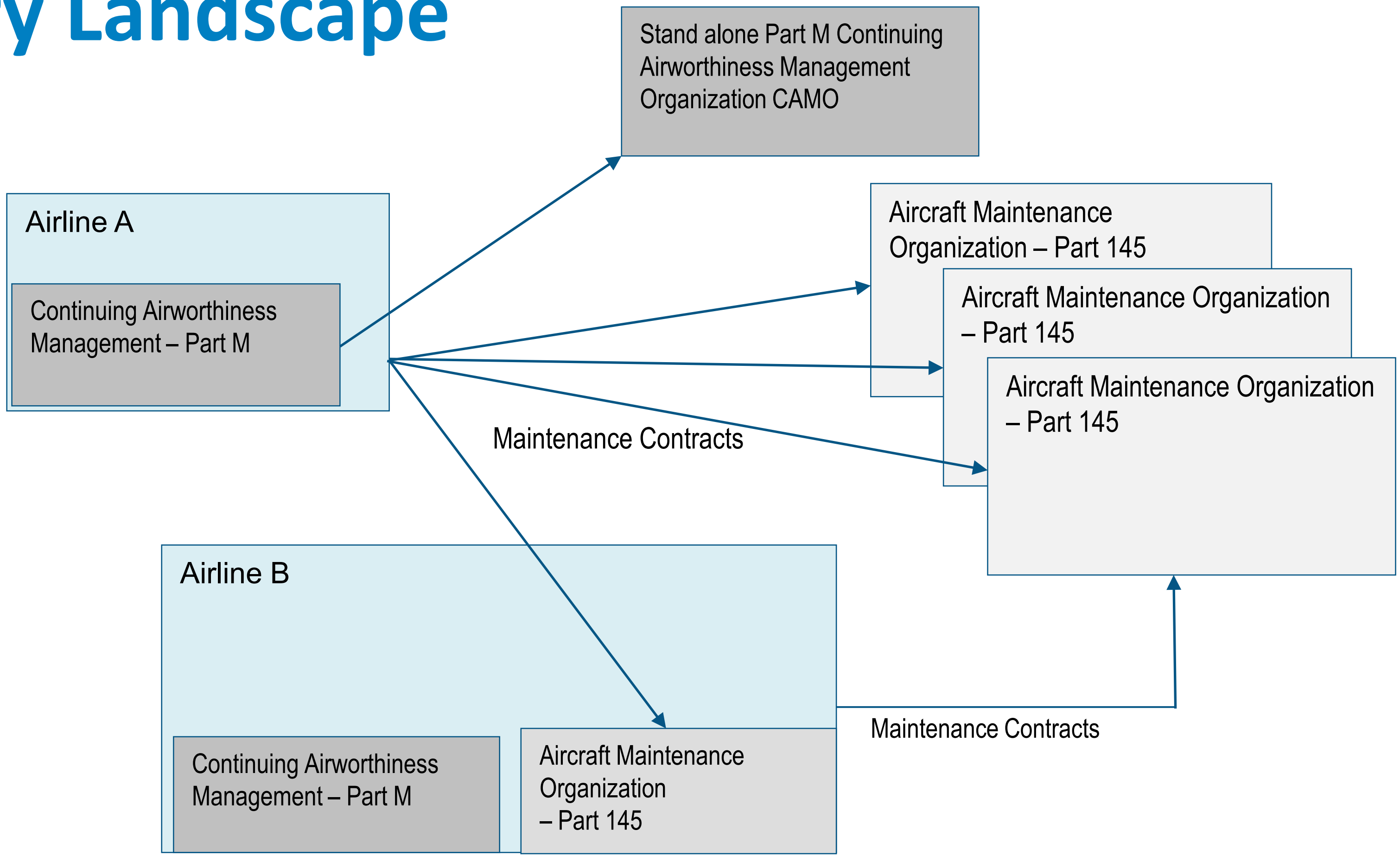
Industry Landscape



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Contents of EASA Part-M

- Annex I (Part-M)
  - GENERAL
  - SECTION A — TECHNICAL REQUIREMENTS
  - SECTION B — PROCEDURE FOR COMPETENT AUTHORITIES
  - APPENDICES TO ANNEX I (Part-M)
  - APPENDICES TO AMCs AND GM TO ANNEX I (Part-M)

Contents of EASA Part-M

- ▼ SECTION A — TECHNICAL REQUIREMENTS
  - ▶ SUBPART A — GENERAL
  - ▶ SUBPART B — ACCOUNTABILITY
  - ▶ SUBPART C — CONTINUING AIRWORTHINESS
  - ▶ SUBPART D — MAINTENANCE STANDARDS
  - ▶ SUBPART E — COMPONENTS
  - ▶ SUBPART F — MAINTENANCE ORGANISATION
  - ▶ SUBPART G — CONTINUING AIRWORTHINESS MANAGEMENT O...
  - ▶ SUBPART H — CERTIFICATE OF RELEASE TO SERVICE — CRS
  - ▶ SUBPART I — AIRWORTHINESS REVIEW CERTIFICATE

Contents of EASA Part-M

- SUBPART A — GENERAL - Scope of the regulation
- SUBPART B — ACCOUNTABILITY
  - M.A.201 Responsibilities
    - This chapter specifies responsibilities with regards to the continuing airworthiness of: aircraft owner, lesee, pilot, operator, commercial operator,
  - M.A.202 Occurrence reporting
    - to Authorities
    - to TC holder

GM M.A.201 Responsibilities

ED Decision 2016/011/

Quick summary table

Select your type of operation and your category of aircraft			**Complex motor-powered aircraft**		**Other-than-complex motor-powered aircraft**	
			Is a CAMO required for the management of continuing airworthiness?	Is maintenance by a maintenance organisation required?	Is a CAMO required for the management of continuing airworthiness?	Is maintenance by a maintenance organisation required?
Commercial operations	CAT	Air carriers licensed in accordance with Regulation (EU) No 1008/2008	Yes, a CAMO is required and it shall be part of the AOC (M.A.201(e))	Yes, maintenance by a Part-145 organisation is required (M.A.201(e))	Yes, a CAMO is required and it shall be part of the AOC (M.A.201(e))	Yes, maintenance by a Part-145 organisation is required (M.A.201(e))
Commercial operations	CAT	CAT other than air carriers licensed in accordance with Regulation (EC) No 1008/2008	Yes, a CAMO is required (M.A.201(f))	Yes, maintenance by a Part-145 organisation is required (M.A.201(f))	Yes, a CAMO is required (M.A.201(h))	Yes, maintenance by a Subpart F or by a Part-145 organisation is required (M.A.201(h))
Commercial operations	Commercial operations other than CAT	Commercial specialised operations	Yes, a CAMO is required (M.A.201(f))	Yes, maintenance by a Part-145 organisation is required (M.A.201(f))	Yes, a CAMO is required (M.A.201(h))	Yes, maintenance by a Subpart F or by a Part-145 organisation is required (M.A.201(h))
Commercial operations	Commercial operations other than CAT	Commercial training organisations (ATOs)	Yes, a CAMO is required (M.A.201(f))	Yes, maintenance by a Part-145 organisation is required (M.A.201(f))	Yes, a CAMO is required (M.A.201(h))	Yes, maintenance by a Subpart F or by a Part-145 organisation is required (M.A.201(h))
Other than commercial operations including limited operations as defined in Article 2(p)			Yes, a CAMO is required (M.A.201(g))	Yes, maintenance by a Part-145 organisation is required (M.A.201(g))	No, a CAMO is not required (M.A.201(i))	No, maintenance by a Subpart F or Part-145 organisation is not required (M.A.201(i))’

Contents of EASA Part-M

- SUBPART C — CONTINUING AIRWORTHINESS
  - M.A.301 Continuing airworthiness tasks
  - M.A.302 Aircraft Maintenance Programme
  - M.A.303 Airworthiness directives
  - M.A.304 Data for modifications and repairs
  - M.A.305 Aircraft continuing airworthiness record system
  - M.A.306 Aircraft technical log system
  - M.A.307 Transfer of aircraft continuing airworthiness records

Contents of EASA Part-M

- SUBPART D — MAINTENANCE STANDARDS
  - M.A.401 Maintenance data
    - AMC M.A.401 Maintenance data
  - M.A.402 Performance of maintenance
    - AMC M.A.402 Performance of maintenance
    - GM M.A.402 Performance of maintenance
  - M.A.403 Aircraft defects
    - AMC M.A.403 Aircraft defects

Contents of EASA Part-M

- SUBPART E — COMPONENTS
  - M.A.501 Installation
    - AMC M.A.501(a) Installation
  - M.A.501(b) Installation
  - M.A.502 Component maintenance
    - AMC M.A.502 Component maintenance
  - M.A.503 Service life limited components .
  - M.A.504 Control of unserviceable components
    - AMC M.A.504(a) Control of unserviceable components

Contents of EASA Part-M

- SUBPART F — MAINTENANCE ORGANISATION
  - M.A.601 Scope
  - M.A.602 Application
  - M.A.603 Extent of approval
  - M.A.604 Maintenance organisation manual
  - M.A.605 Facilities
  - M.A.606 Personnel requirements
  - M.A.607 Certifying staff and airworthiness review staff
  - M.A.608 Components, equipment and tools
  - M.A.609 Maintenance data
  - M.A.610 Maintenance work orders
  - M.A.611 Maintenance standards
  - M.A.612 Aircraft certificate of release to service
  - M.A.613 Component certificate of release to service
  - M.A.614 Maintenance and airworthiness review records
  - M.A.615 Privileges of the organisation
  - M.A.616 Organisational review
  - M.A.617 Changes to the approved maintenance organisation
  - M.A.618 Continued validity of approval
  - M.A.619 Findings

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Contents of EASA Part-M

- SUBPART G — CONTINUING AIRWORTHINESS MANAGEMENT ORGANISATION
  - M.A.701 Scope
  - M.A.702 Application
  - M.A.703 Extent of approval
  - M.A.704 Continuing airworthiness management exposition
  - M.A.705 Facilities
  - M.A.706 Personnel requirements
  - M.A.707 Airworthiness review staff
  - M.A.708 Continuing airworthiness management
  - M.A.709 Documentation
  - M.A.710 Airworthiness review
  - M.A.711 Privileges of the organisation
  - M.A.712 Quality system
  - M.A.713 Changes to the approved continuing airworthiness organisation
  - M.A.714 Record-keeping
  - M.A.715 Continued validity of approval
  - M.A.716 Findings

Contents of EASA Part-M

- SUBPART H — CERTIFICATE OF RELEASE TO SERVICE — CRS
  - M.A.801 Aircraft certificate of release to service
  - M.A.802 Component certificate of release to service
  - M.A.803 Pilot-owner authorisation

Contents of EASA Part-M

- SUBPART I — AIRWORTHINESS REVIEW CERTIFICATE
  - M.A.901 Aircraft airworthiness review
  - M.A.902 Validity of the airworthiness review certificate
  - M.A.903 Transfer of aircraft registration within the EU
  - M.A.904 Airworthiness review of aircraft imported into the EU
  - M.A.905 Findings

EASA Part M in Details

- Let us review the actual requirements:
  - EASA Part M regulation
  - EASA CAME guidance material
  - Appendix XI to AMC M.A.708(c) — Contracted maintenance

- Excercise:
  - Development of CAME Approval Check list
  - Maintenance Contract Review Check list

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FDM – Flight Data Monitoring Programs

Omer Pita and Salvador Alepuz
Airworthiness Experts

Flight Data Monitoring

- A systematic method of accessing, analysing and acting upon information obtained from digital flight data records of routine flight operations to improve safety.
- It involves proactive and timely use of flight data to identify and address operational risks before they can lead to incidents and accidents.

ICAO Annex 6, Part 1.

- **To establish and maintain a flight data analysis programme as part of accident prevention and flight safety programme.**
- Recommendation for a/c over 20 tonnes MTOW.
- **Standard for a/c over 27 tonnes MTOW.**
  - Data is to be used for flight safety purposes only.
  - Data analysis is to be NON-PUNITIVE.
  - Operators are to establish internal safeguards.

EC No 965/2012

ORO.AOC.130 Flight data monitoring — aeroplanes

- (a) The operator shall establish and maintain a flight data monitoring system, which shall be integrated in its management system, for aeroplanes with a maximum certificated take-off mass of more than 27 000 kg.
- (b) The flight data monitoring system shall be non-punitive and contain adequate safeguards to protect the source(s) of the data.

Objectives of FDM

- → Identify areas of operational risk and quantify current safety margins.
- → Identify and quantify operational risks by highlighting when non-standard, unusual or unsafe circumstances occur.
- → Use the FDM information on the frequency of occurrence, combined with an estimation of the level of severity, to assess the safety risks and to determine which may become unacceptable if the discovered trend continues.

Objectives of FDM

- Put in place appropriate procedures for remedial action once an unacceptable risk, either actually present or predicted by trending, has been identified.
- Confirm the effectiveness of any remedial action by continued monitoring.

Sensitivity of flight data information

- Recorded flight data are very sensitive information that has a potential to be misused for blaming and mistreating the operating pilots
- This clearly is not the objective of the FDM program, therefore it shall be clearly stated in operator's safety policy and in FDM program that operator supports and practices non-punitive approach and that the sole purpose of FDM is to enhance safety
- FDM program shall not be used to rutinely check pilot performance or be the basis for disciplinary processes

Sensitivity of flight data information

- Access to identifiable data shall be restricted the safety professionals on the „need to know" basis,
- Flight Data shall be de-identified and shall remain anonymous unless specified otherwise by law.
- De-identified Flight Data may be used in the production of reports or educational publications or briefing material as approved by the Safety Manager.
- All identifiable event data shall be destroyed within 6 months of completion of the related flight
- De-identified raw data or event data used to substantiate statistical information from FDM Reports, may be kept for longer periods

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Memorandum of Agreement with Pilots Union Key Points

An agreement should be established between the Company and Pilots Union, it should contain following elements:

- → Objectives of the FDM System
- → Establish data access rights
- → Emphasize Just Culture
- → Confidentiality Clause
- → Define Escalation Process
- → Define Union Rep involvement

Who can access the flight data

- Operating flight crew – data from the flights that they performed
- Safety Manager and FDM safety experts
- State accident investigation officials during accident/incident investigations
- The access to the data can be requested (access to be granted by FDM program management) by Engineering/Maintenance in case of technical occurences or for troubleshooting purposes.

FDR Analysis Techniques

- **Exceedence Detection** by observing the deviations from flight manual limits and standard operating procedures.
- A set of core events should be selected to cover the main areas of interest to the operator.
- The event detection limits should be continuously reviewed to reflect the operator’s current operating procedures.

FDR Analysis Techniques

- **All Flights Measurement** is a system used to define what is normal practice. This may be accomplished by retaining various snapshots of information from each flight.
- **Statistics to support analysis** represents a set of statistical data collected to support the analysis process (eg. number of flights flown and analysed, aircraft and sector details sufficient to generate statistically significant rate and trend information).
  - 2. A set of raw data from every flight analysed.
  - 3. Statistical analysis of data.

Assessment and Process Control Tools

- The effective assessment of information obtained from digital flight data requires adequate hardware and dedicated software solutions.
- A software should include: data verification and validation, data processing, data displays and access to interpretative material .

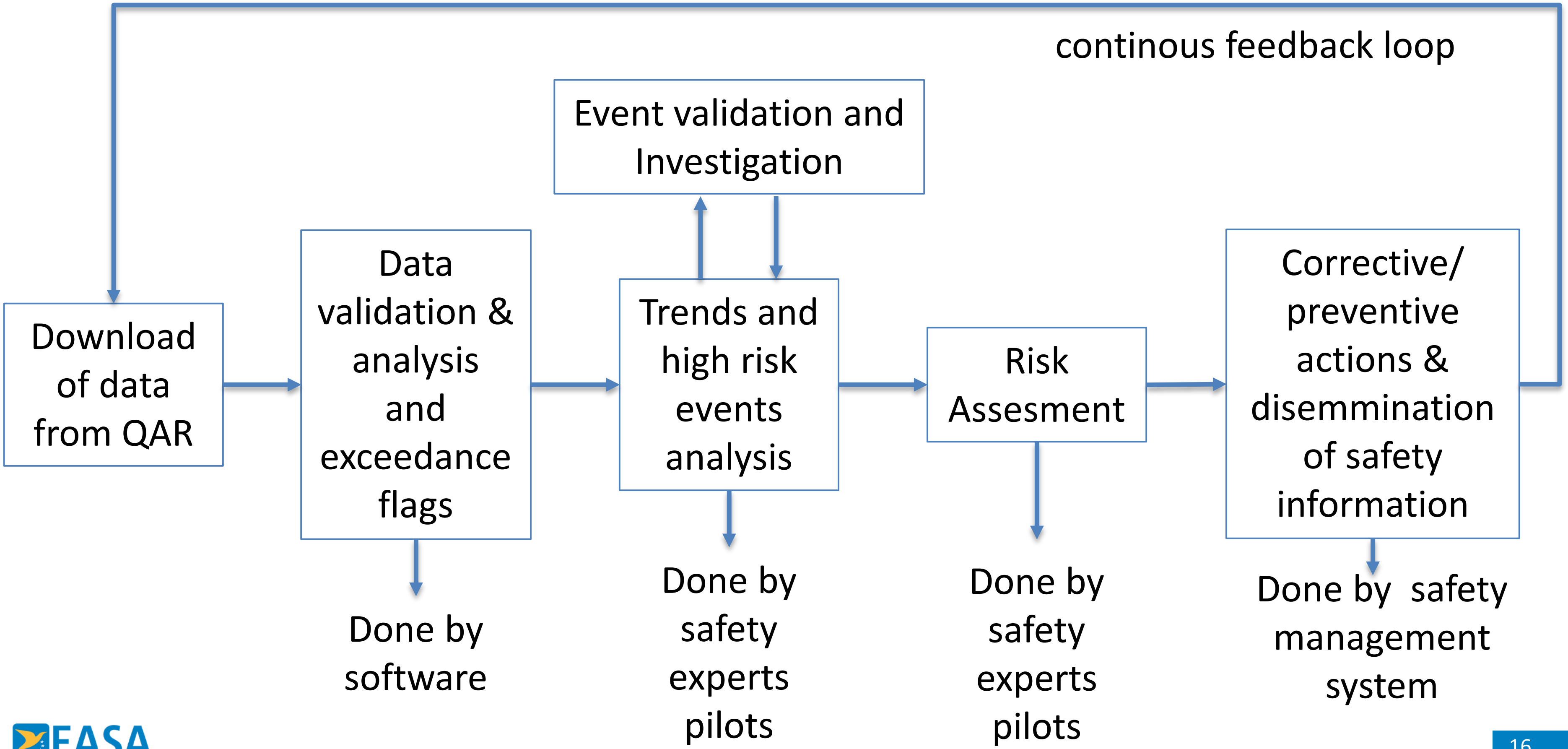
Correlation between FDM and MOR’s

- In theory, most significant FDM events should be also reported as MOR’s.
- It is a good indicator of the current level of the reporting culture
- In case that there is a lack of submitted MOR’s compared to FDM, it should be brought to the attention of pilots that they should pay more attention to the timely reporting of the occurences.

FDM elements

- **Administration**: Support staff manage raw data, create statistical reports, cross check with MOR’s
- **Auditing**: Validation of events flagged up by the software
- **Investigation**: ‘gatekeepers’ carry out crew contacts for selected FDM events
- **Communication**: Facts & lessons learned from investigation into memos and newsletters; management review meeting (inputs to training)
- **Improvement**: changes to the procedures, policies, and staff training

Flight Data Analysis Program Flow Chart



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Data processing flow

1 Step 1 - Analyst	2 Step 2 - Analyst	3 Step 3 – Pilot Rep	4 Step 4 - FSO
Check for correct data capture and reconciliation	Validate Data	Validate Event	Record FDM analysis against ASR
Escalate to the IT FDM team for issues	Escalate to PR if necessary by raising a flight action	Close Flight	Crew Feedback
Otherwise raise work order with Tech Services	Escalate to ASM if a significant event	Request ASR where required or necessary	Liaise with Management
		Log activity for auditable purposes	

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Analysis tools – types of information used for analysis

- Exceedence and event detection.
- Measurements from every flight.
- Archived full flight data.
- Statistical information.
- Rates & Trends.
- Ad-hoc analysis.

Exceedence or Event Detection

- A computer program scans FDR data for:
  - Deviations from SOPs.
  - Exceedences of Flight Manual Limits.
  - Warnings and their precursors
  - Unusual or unexpected situations.
- This is basis of most FDM programmes

Example Events

Event Group	Description
Flight Manual Speed Limits	Vmo exceedence
	Mmo exceedence
	Flap placard speed exceedence
	Gear down speed exceedence
	Gear up/down selected speed exceedence
Flight Manual Altitude Limits	Exceedence of flap/ slat altitude
	Exceedence of maximum operating altitude
High Approach Speeds	Approach speed high within 90 sec of touchdown
	Approach speed high below 500 ft AAL
	Approach speed high below 50 ft AGL
Low Approach Speed	Approach speed low within 2 minutes of touchdown
High Climb-out Speeds	Climb out speed high below 400 ft AAL
	Climb out speed high 400 ft AAL to 1000 ft AAL
Low Climb-out Speeds	Climb out speed low 35 ft AGL to 400 ft AAL
	Climb out speed low 400 ft AAL to 1500 ft AAL
Take-off Pitch	Pitch rate high on take-off
Unstick Speeds	Unstick speed high
	Unstick speed low
Pitch	Pitch attitude high during take-off
	Abnormal pitch landing (high)
	Abnormal pitch landing (low)
Bank Angles	Excessive bank below 100 ft AGL
	Excessive bank 100 ft AGL to 500 ft AAL
	Excessive bank above 500 ft AGL
	Excessive bank near ground (below 20 ft AGL)

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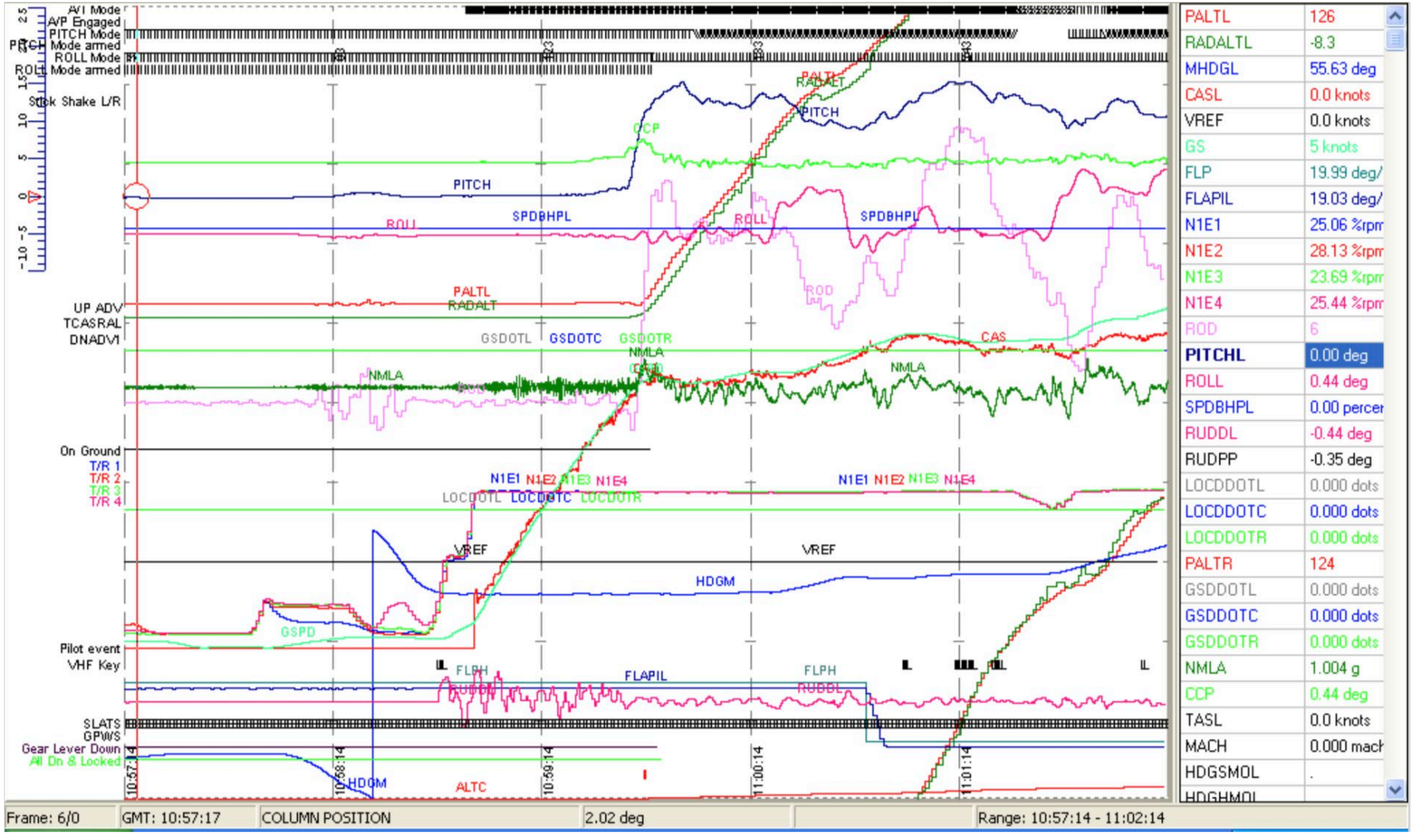
Trace Presentation



Important Aspects of the FDM Analysis Process

- Levels of significance - not all exceedences are equal.
- Data security and anonymity - the conflict between analysis and de-identification.
- Phased de-identification with time - to allow initial follow-up.
- Merging FDM data with other safety information e.g. occurrence reports, technical log reports.
- Also use of FDM data for engineering, organisational and financial benefits.

Aircraft Equipment used for FDM

- Equipment used to obtain FDM data will range from an already installed full Quick Access Recorder, in a modern aircraft with digital systems, to a basic crash protected recorder in an older or less sophisticated aircraft. The analysis potential of the reduced data set available in the latter case may reduce the safety benefits obtainable.
- The operator shall ensure that FDM use does not adversely affect the serviceability of equipment required for accident investigation.

History of FDR

- 1960’s - The earliest recording systems used analogue encoding formats developed by the various manufacturers, with no standardisation.
- 1970: the ARINC1 573 specification was developed by industry to standardise the encoding format of flight data on CAT accident protected recorders,
- 1979: ARINC 573 was superseded by ARINC 717 which is still in use today with emerging ARINC 767 standard (B787)

Number of the recorded parameters

- Regulatory requiremets (EASA, FAA) require around 80 parameter categories.
- Many aircraft types record more:
  - Airbus A320 family = >450
  - Boeing 777 = 1,400
  - Airbus A380 = 2,000
  - Boeing B787 = 2,200

Basic Parameters for FDM

- Most of FDM can be done using relatively small number of recorded parameters, such as:
  - airspeed,
  - altitude,
  - heading,
  - flap,
  - landing gear,
  - pitch,
  - roll,
  - weight-on-wheels,
  - autopilot status.

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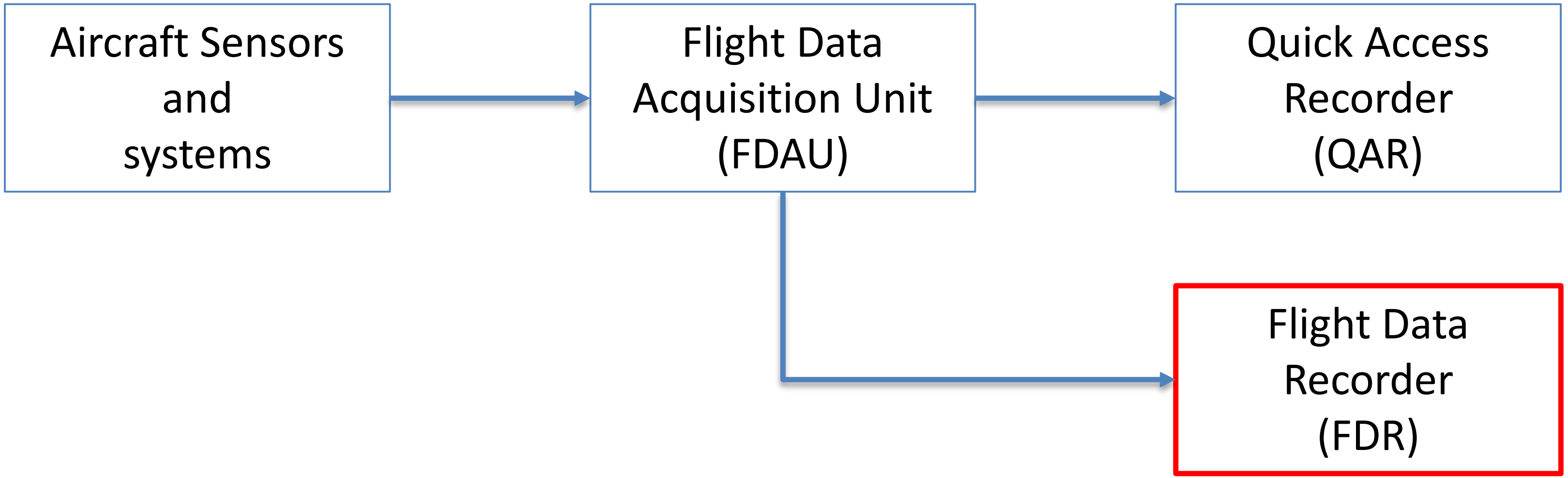
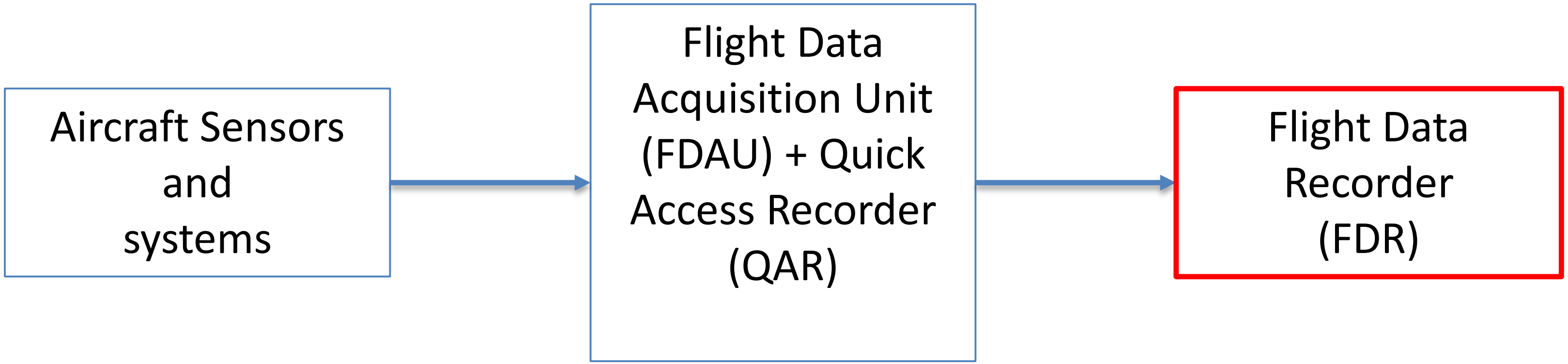
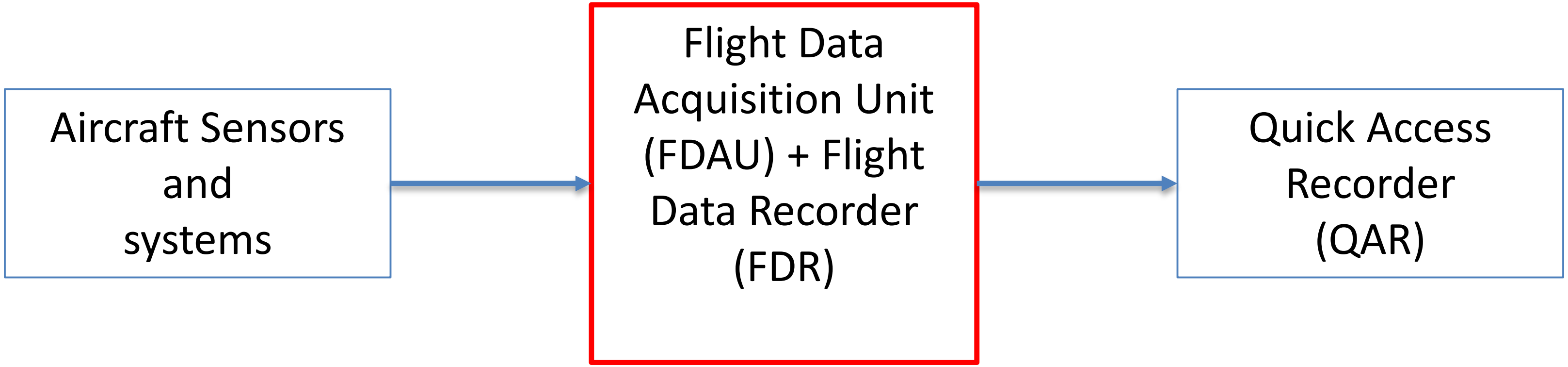
Recording System (typical)



Recording System



Recording System



Quick Access Recorder (QAR)

- QAR is not required by regulation;
- It is not accident protected like FDR;
- Compared to the FDR, may be fited in more easily accessible locations for prompt access and media changes (cockpit, cabin locker...)
- **First Generation QAR's**
  - Tape system, using a removable cartridge.
  - Reliable, but limited recording capacity.

Quick Access Recorder (QAR)

- **Second Generation - Optical QAR (1990's)**
- 3.5" removable magneto optical disk (128-230mb).
- Greater recording capacity compared to tape.
- **Third Generation – PCMCIA QAR (2000)**
- FLASH memory
- Good reliability
- >200 hrs from a 230mb card.
- **Forth Generation – various wireless solutions, micro and mini QAR's**

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End of presentation

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Minimum Equipment List

Omer Pita and Salvador Alepuz
Airworthiness Experts

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Useful Definitions

- Configuration deviation list (CDL).
  - A list established by the organization responsible for the type design with the approval of the State of Design which identifies any external parts of an aircraft type which may be missing at the commencement of a flight, and which contains, where necessary, any information on associated operating limitations and performance.
- Master minimum equipment list (MMEL).
  - A list established for a particular aircraft type by the organization responsible for the type design with the approval of the State of Design containing items, one or more of which is permitted to be unserviceable at the commencement of a flight. The MMEL may be associated with special operating conditions, limitations or operational/maintenance procedures.

Useful Definitions cont’d

- Minimum equipment list (MEL).
  - A list which provides for the operation of aircraft, subject to specified conditions, with particular equipment inoperative, prepared by an operator in conformity with, or more restrictive than, the MMEL established for the aircraft type.
  - Note:
    - The MEL is derived from the MMEL and is applicable to an individual operator. The operator’s MEL takes into consideration the operator’s particular aircraft configuration, operational procedures and conditions. When approved and authorized for use, the MEL permits operation of the aircraft under specified conditions with certain inoperative equipment.

Purpose of MEL

- Civil Aviation Regulations permit the approval of an MEL in that compliance with all the aircraft equipment requirements is not necessary in the interest of safety for a particular operation.
- Through the use of appropriate conditions or limitations, the MEL provides for improved operations schedule reliability and aircraft utilization with an equivalent level of safety.
- This process is possible because of the installation of additional and redundant instruments, equipment and/or systems in present transport aircraft.
- Without an approved MEL, inoperative equipment would ground the aircraft until repair or replacement of the non-functioning equipment.

Purpose of MEL (JAA TGL 26)

- The MEL is a joint operations and maintenance document prepared by an operator to:
  - identify the minimum equipment and conditions for an aircraft to maintain the Certificate of Airworthiness in force and to meet the operating rules for the type of operation;
  - define operational procedures necessary to maintain an acceptable level of safety and to deal with inoperative equipment; and
  - define maintenance procedures necessary to maintain an acceptable level of safety and procedures necessary to secure any inoperative equipment.

MEL General

- MEL is for a specific make and model of aircraft and for a specific configuration and is approved by a stamp and/or signature from the CAA inspector authorising its use by the operator.
- The MEL needs to be available to flight crew, maintenance personnel and personnel responsible for operational control. The MEL also needs to include instructions for its use, including defects entry, categories, and actions to be taken (maintenance or operation) and placarding.

MMEL – MEL Relationship

- The MEL is customized from the MMEL to the operator's specific aircraft, aircraft equipment , modifications and operating environment and may be dependent upon the route structure, geographic location, and number of airports where spares and maintenance capability are available.
- Where the MMEL cannot address some of the variables, it uses a standard terms such as "As required by Regulations". The operator is required to meet the requirements of the applicable CAA regulations to develop operations and/or maintenance procedures.
- The operator shall submit a training programme for maintenance personnel on the appropriate policies and procedures in using a MEL.

Rectification Interval Categories

- **Category A**
- No standard interval is specified, however, items in this category shall be rectified in accordance with the conditions stated in the MMEL. Whenever the time interval is specified in calendar days, it shall start at 00:01 on the calendar day following the day of discovery.
- **Category B**
- Items in this category shall be rectified within three consecutive calendar days, excluding the day of discovery.

Rectification Interval Categories

- **Category C**
- Items in this category shall be rectified within 10 consecutive calendar days, excluding the day of discovery
-
- **Category D**
- Items in this category shall be rectified within 120 consecutive calendar days, excluding the day of discovery.
-

Rectification Interval Extensions

- It is recognized that while MEL item rectification interval categories have been established, it may not be possible in every case to rectify aircraft in the time allotted for each MEL item.
- Several factors may influence the operator's ability to comply with the specified interval.
  - Parts shortages from manufacturers clearly outside the operator's control.
  - Long lead times for ordered parts
  - Inability to obtain equipment necessary for proper troubleshooting and repair.
- Only in such justified cases, it is allowed to extend rectification interval up to 100% by the operator and greater extension only by the authority.

Equipment Included and not included in the MMEL / MEL

- Included:
  - Equipment that is required for the safe operation of the aircraft
- Not included:
  - Non-safety related equipment which does not affect airworthiness or operation of the aircraft (entertainment, galley equipment...)
- However:
  - if the non-safety related equipment has another function related to safety (such as use of the entertainment system for passenger briefings) then this item must be included in the MMEL/ME
- Ultimately:
  - all items related to the airworthiness of the aircraft and not included in the MMEL are automatically required to be operative prior to flight

Placarding

- Inoperative items should be placarded to inform crew members of equipment condition as appropriate. When they are accessible to the crew in flight, the control(s), and/or indicator(s) related to inoperative unit(s) or component(s) should be clearly placarded.
- Placarding should be carried out in accordance with the placarding procedures established and set out in the operator's approved manuals.
- The method of placarding control should ensure that all inoperative items are placarded and placards are removed and accounted for when the defect is cleared.

Operational and Maintenance Items

- Any item of equipment in the MEL which, when inoperative would require an operational or maintenance procedure to ensure an acceptable level of safety, should be so identified in the "remarks" or "exceptions" column of the MEL. This will normally be:
- "(O)" for an operational procedure, or
- "(M)" for a maintenance procedure.
- (O)(M) means both operational and maintenance procedures are required.

Training

- Operators should develop a MEL training programme for **ground personnel**, to be included in the CAME/MOE and Operations Manual, as appropriate, which must be approved prior to an operator receiving approval to operate with a MEL.
- Operators should provide crew members with MEL training and should detail such training in their Operations Manual. The training should include the purpose and use of a MEL, instruction on company MEL procedures, elementary maintenance procedures, and pilot-in-command responsibility.

MEL acceptability general criteria

The general criteria for MEL acceptability are as follows:

a) Equally or more restrictive.
The operator's MEL must not be less restrictive than the MMEL, the [State CARs], operations specifications, the approved flight manual limitations, certification maintenance procedures, or airworthiness directives (AD).

b) Appropriate.
The MEL must be appropriate to the individual aircraft make and model. It should take into account the service bulletins implemented and the equipment installed.

c) Specific.
The operator's operations ("O") and maintenance ("M") procedures must be specific to the aircraft and the operations conducted.

MEL Approval Process – Airworthiness Aspects

→ In the application for the approval of a MEL, the operator's MEL should:

a) identify the minimum equipment and conditions for an aircraft to maintain conformity with the standards of airworthiness and to meet the operating rules for the type of operation;

b) define operational procedures necessary to maintain the required level of safety and to deal with inoperative equipment; and

c) define maintenance procedures necessary to maintain the required level of safety and procedures necessary to secure any inoperative equipment.

Minimum equipment list evaluation – guidance

- The applicant shall submit a copy the latest MMEL issued by the design organization. The equipment allowed to be inoperative for flight in the MEL cannot be less restrictive than those established in the MMEL for the aircraft type.
- The MMEL will serve as the basis for the approval of the MEL.
- The applicant must address all “as required by Regulations” by making the appropriate remarks as required by CAA regulations.
- All items with (M) mark should have appropriatewritten maintenance procedures enclosed to (or integrated with) MEL.
- Link to check list

End of presentation

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Non-compliance Management and Corrective Action Procedure

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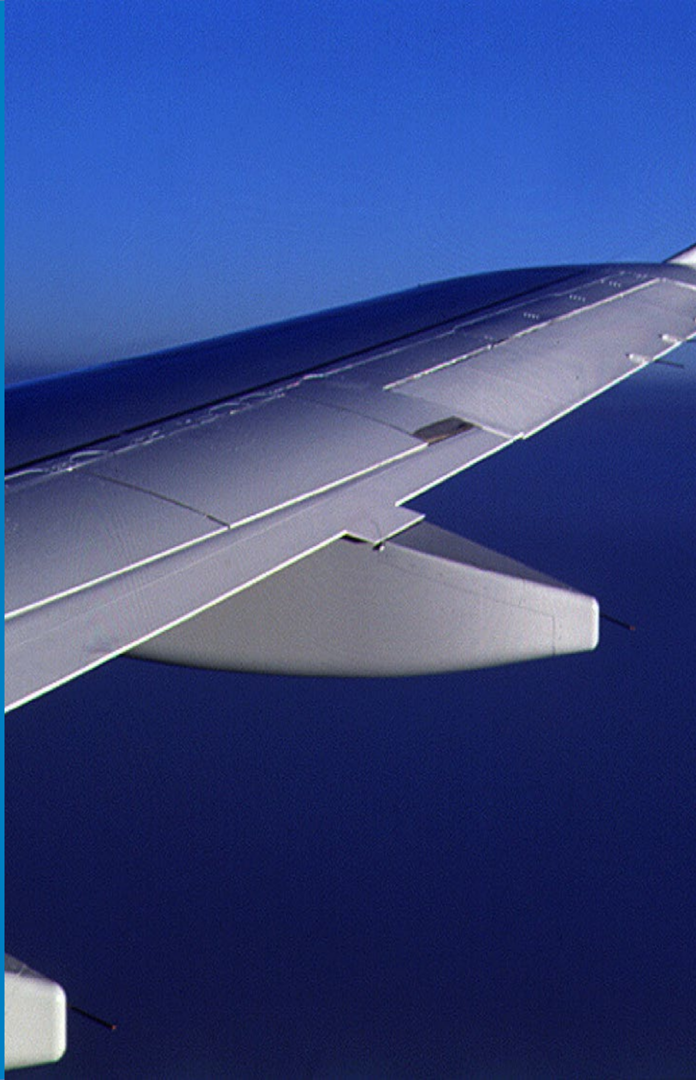
Handling the Audit Report



Issuing the Audit Report

Draft Audit Report

- Audit Team Leader compiles and prepares draft Audit Report and distributes it to Responsible Manager

Comments and Ammendments

- Responsible Manager gives comments and proposes ammendments with regard to the findings.

Final Draft Audit Report

- Audit Team Leader finalyses the Audit Report and distributes it to Quality Manager

Audit Report

- Quality Manager endorses final draft and distributes the final Audit Report to responsible managers

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Using Form to Process Findings Data

- Quality Manager is responsible that corrective action process is monitored and controlled.
- The most efficient way to have control over the process is to have all the data centralized under one system within the organization which is managed by Quality Manager
- This requires uniform format of standardized data to be communicated by the all departments of the organization.
- To facilitate this it is necessary to transfer audit findings from the Audit Report into a form and/or computer database.

Examples of Finding Forms

CERN
CH-1211 Geneva 23
Switzerland

the Large Hadron Collider project

LHC Project Document No.
LHC-0000002462 v.0

EDMS Document No.
348109

Nonconformance Number
NC_CDPT_1005_1

Nonconformance Report

IDENTIFICATION	
1. Originator Name: Pierre Pugnat	3. Date: May 7th 2002
2. Contractor/Supplier: Consortium Alstom-Jeumont	4. NC No: NC_CDPT_1005_1
5. Contract No: F301	
6. Part description: Cryodipole LBBR	8. Qty: 1
7. Part ID: HCMBB_A001-01000005	9 Dwg No: NA

10. Found during what activity:
- ☐ Incoming inspection
- ☐ In-process inspection
- ☐ Final inspection
- ☒ Other: Cold Tests at CERN

11. Description of nonconformance (use continuation page if necessary)
The quench performance around 1.9 K of the cryo-dipole HCMBB_A001-01000005 is below the acceptance criteria defined in the technical specification IT-2708 (see continuation page).

12. Action taken to prevent misuse (use continuation page if necessary)
The standard acceptance test procedure for pre-series LHC cryo-dipoles was stopped after 7 "training" quenches. HCMBB_A001-01000005 was warmed up and disconnected from the tests bench.

DISPOSITION		
13 ☐ Use-as-is	☒ Return to supplier	Responsible Manager
☐ Repair	☐ Reject	Name: Andrzej Siemko
☐ Rework		Date: 24 May 2002

14. Approval of USE-AS-IS disposition	Project Engineer	Project Management
☐ Non-critical NC	Name: Michele Modena	Name: Jos Vlogaert
☒ Critical NC	Date: 24 May 2002	Date: 24 May 2002

15. Approval of repair, rework, return to supplier, rejection disposition		
Project Engineer	Name: Michele Modena	Date: 24 May 2002

CORRECTIVE/PREVENTIVE ACTION

16. Description of proposed action (use continuation page if necessary)
De-collaring, visual inspection of the Lower pole of the aperture 2 (outer and inner layers, see non-conformance continuation page for a more precise defect location) and replacement of this pole.

17. Approval of corrective/preventive action		
Project Engineer	Name: Michele Modena	Date: 24 May 2002

CLOSING THE NONCONFORMANCE

18. Planned disposition has been completed and corrective/preventive action has been initiated		
Responsible Manager	Name: Andrzej Siemko	Date:

IRREGULARITY REPORT
CORRECTIVE ACTION REQUEST
FOLLOW UP PROCEDURE

No:

Operator

Irregularity or non-compliance:

Recommendation:

Date:	Department:	Resp. Manager	Reported by:	Reference Item	Priority level

Please forward report to all involved, appropriate QAM and QM

Corrective Actions:

Due to:

Responsible Dept. Manager

Responsible Person(s)

Date:

QAM signature:

Follow-up:

1st check ☐ Ok ☐ Not ok	Extended to:	Date:	QAM sign.
2nd check ☐ Ok ☐ Not ok	Extended to:	Date:	QAM sign.
Closing date:	☐ Action Plan updated:		QAM sign.

OD-QMS-004/0

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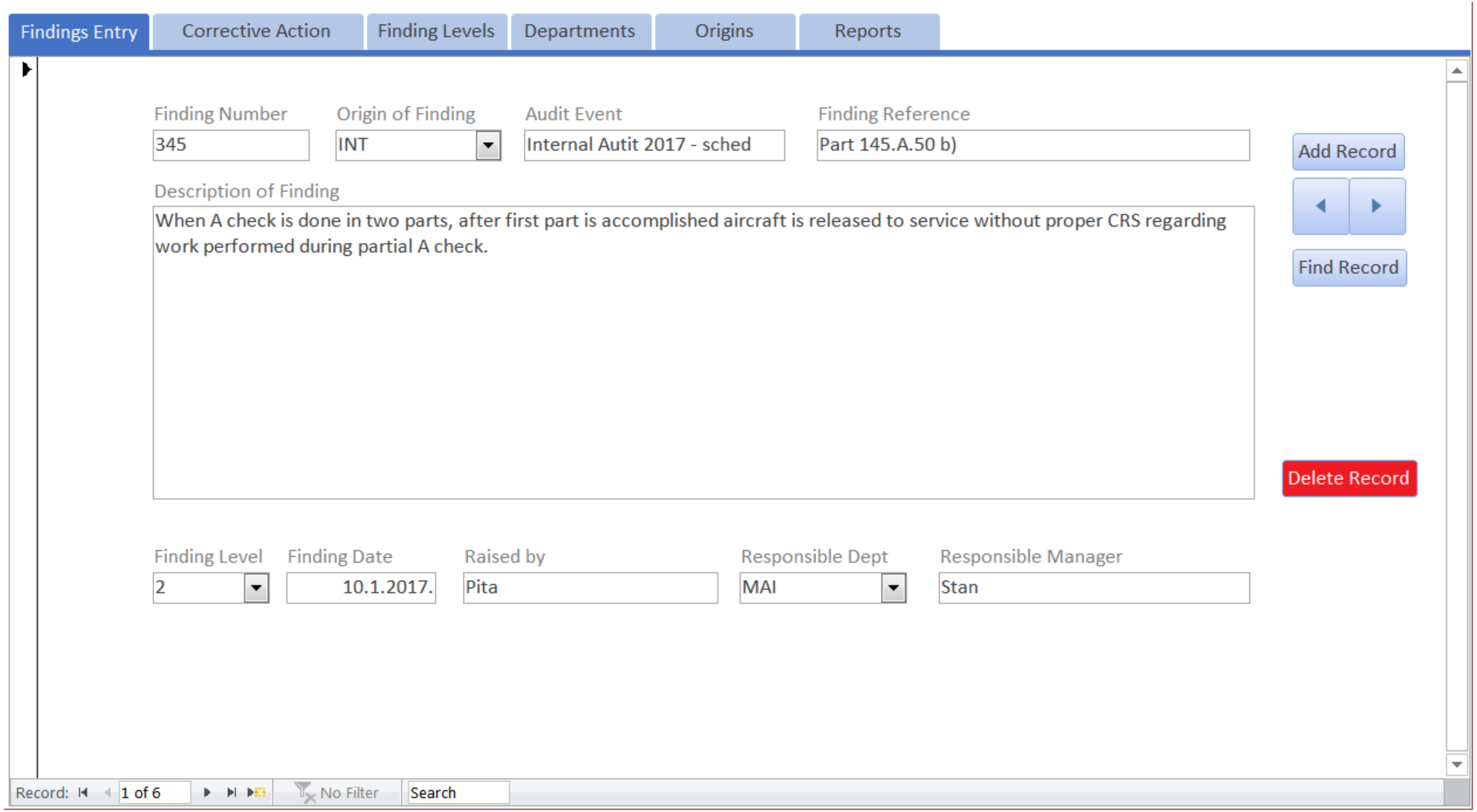
Example of Computer Application



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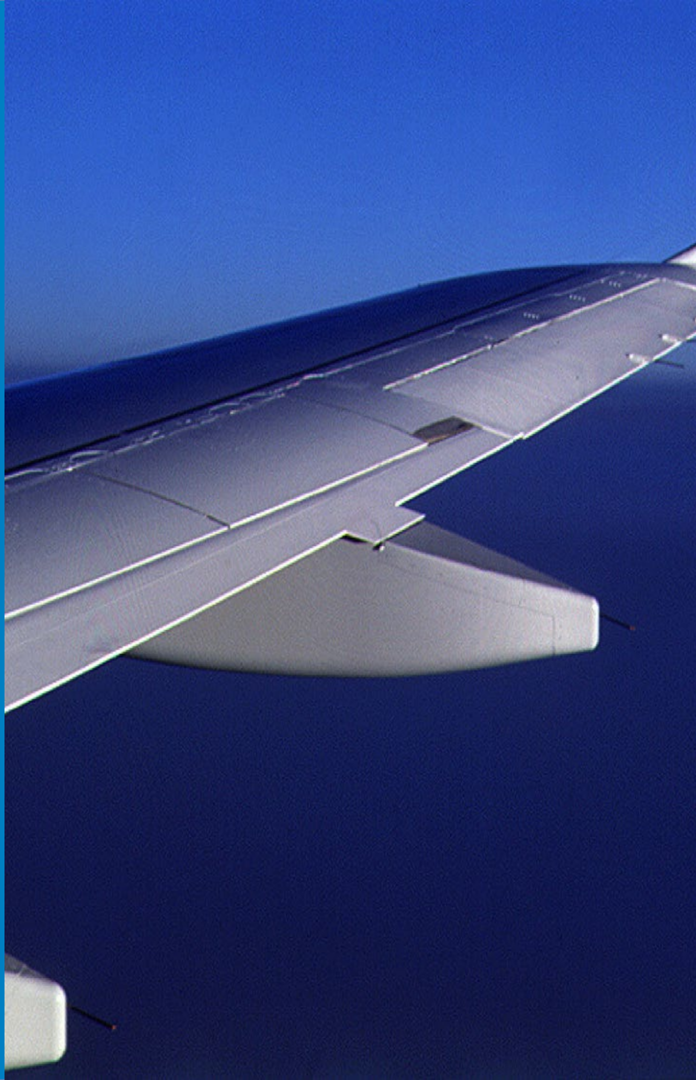
Noncompliance management



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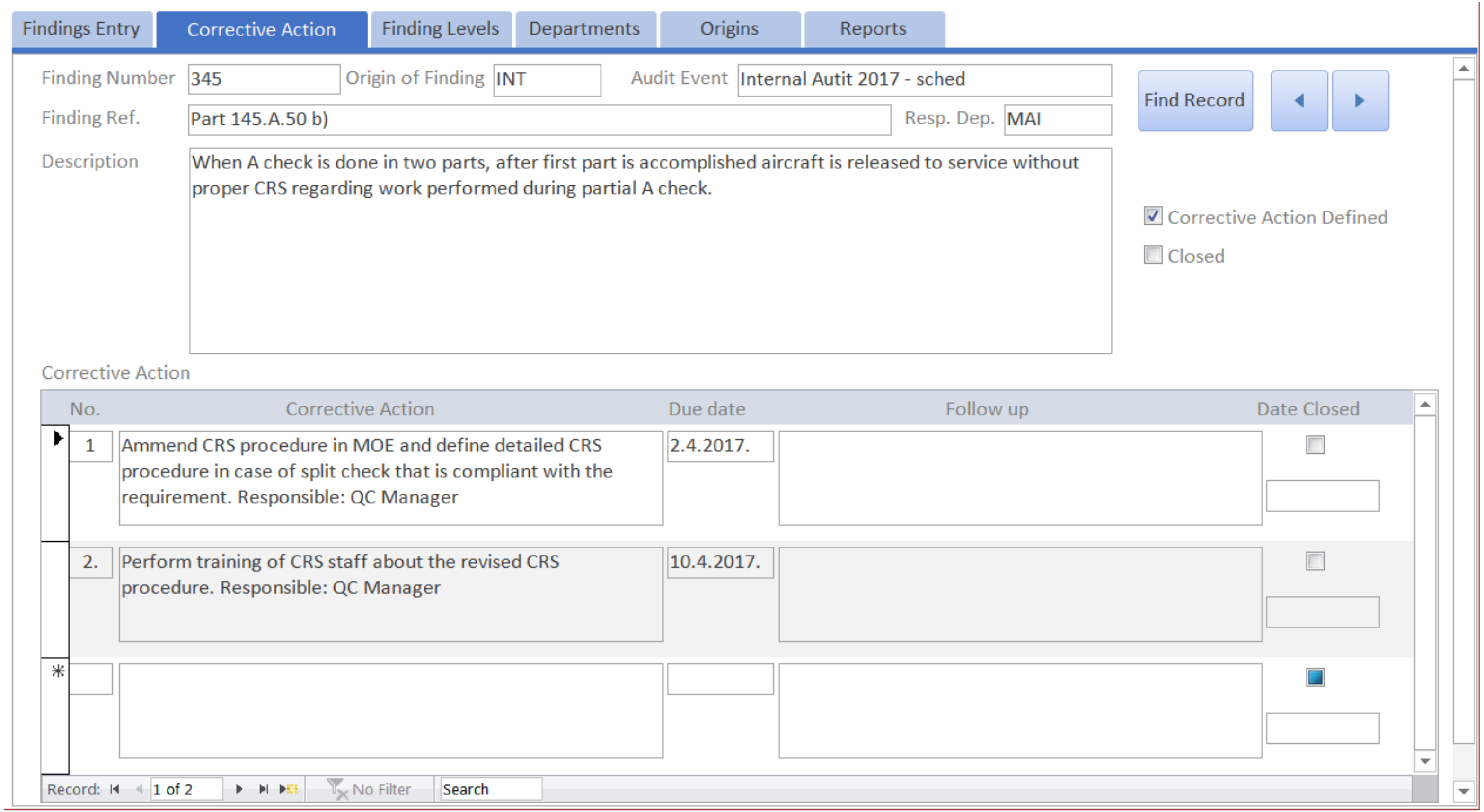
Responsibilities for Corrective Actions

- Quality Manager has overall responsibility for monitoring, managing the process and reporting to the management
- Responsible manager is responsible to:
  - make proper analysis of finding
  - define appropriate corrective actions
  - Once corrective actions are approved, to perform corrective actions within due time
- Lead Auditor and/or Quality Manager are responsible
  - Assess and approve proposed corrective actions
  - Verify that corrective actions have been carried out in satisfying manner
- Accountable Manager is responsible for the overall functioning and the outcome of the process

Administration of Noncompliance's

- Depending on the size of the organization, number of active open findings can be in the range of hundreds.
- It is mandatory that organization can demonstrate full control and can account for any of open findings in terms of current status of corrective actions.
- Therefore, there must be a system in place which enables Quality Manager to report on status of any noncompliance at any time.
- Also, the system must enable Quality Manager to monitor timeliness of corrective actions and to request feedback from Responsible Manager on progress of overdue corrective actions.
- A computer software is best tool for establishing such control.
- It can be simple excel table for small organizations or robust database application for large organizations.

Example Database Application Screen



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Sample Status Report

Compliance Monitoring Status List
Open findings with corrective actions defined

Finding No	Origin of Finding	Audit Event	Description of Finding				
345	INT	Internal Autit 2017 - sched	When A check is done in two parts, after first part is accomplished aircraft is released to service without proper CRS regarding work performed during partial A check.	Finding Level	2	Department	MAI
				Raised by	Pita	Resp. Mgr	Stan
				Finding Date	10.1.2017.		

Item No		Corrective action	Due date	Follow up	Closed	Date Close
Item No	1	Ammend CRS procedure in MOE and define detailed CRS procedure in case of split check that is compliant with the requirement. Responsible: QC Manager	2.4.2017.		☐	
Item No	2.	Perform training of CRS staff about the revised CRS procedure. Responsible: QC Manager	10.4.2017.		☐	

31. siječanj 2017.

Page 1 of 1

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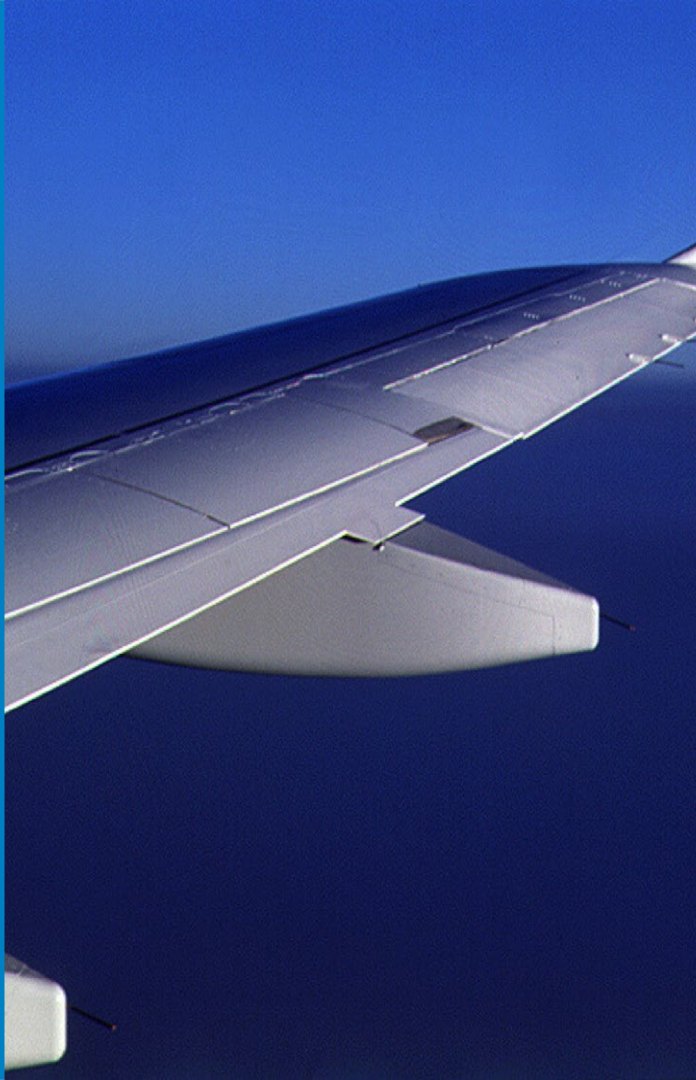
Root cause analysis



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Methods for Root Cause Analysis

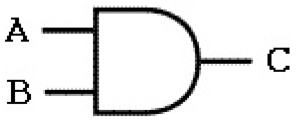
- In order to determine proper corrective action, it is necessary to find the root cause of the noncompliance.
- There are many tools that may be used for root cause analysis, such as:
  - Fault Tree Analysis (FTA)
  - Event Tree Analysis (ETA)
  - Why-Because Analysis (WBA)
  - 5Whys

Fault Tree Analysis

- Fault tree analysis (FTA) is a widely used **top down**, deductive failure analysis in which an undesired state of a system is analyzed using Boolean logic („true”/”false” values with operators „and”, „or” and „not”) to combine a series of lower-level events.
- This analysis method is mainly used in the fields of safety engineering and reliability engineering to understand how systems can fail or have failed, to identify the best ways to reduce risk.
- In aerospace, the term "system Failure Condition" is used for the top event of the fault tree. These conditions are classified by the severity of their effects. The most severe conditions require the most extensive fault tree analysis. These "system Failure Conditions" and their classification are often previously determined in the functional Hazard analysis.

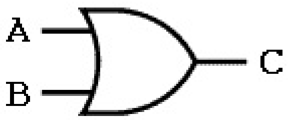
Basic Boolean Logic Operators

AND



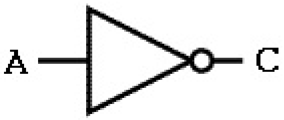
Inputs		Output
A	**B**	**C**
0	0	0
0	1	0
1	0	0
1	1	1

OR



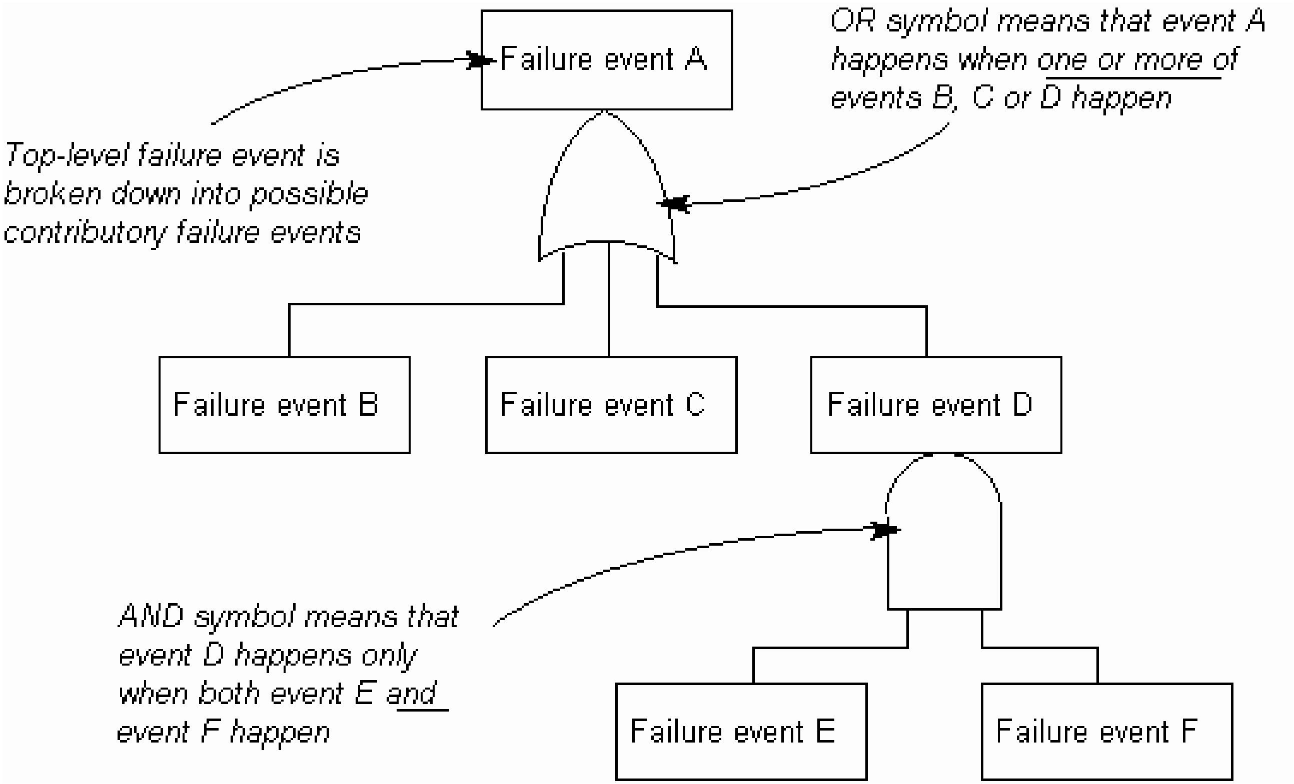
Inputs		Output
A	**B**	**C**
0	0	0
0	1	1
1	0	1
1	1	1

NOT

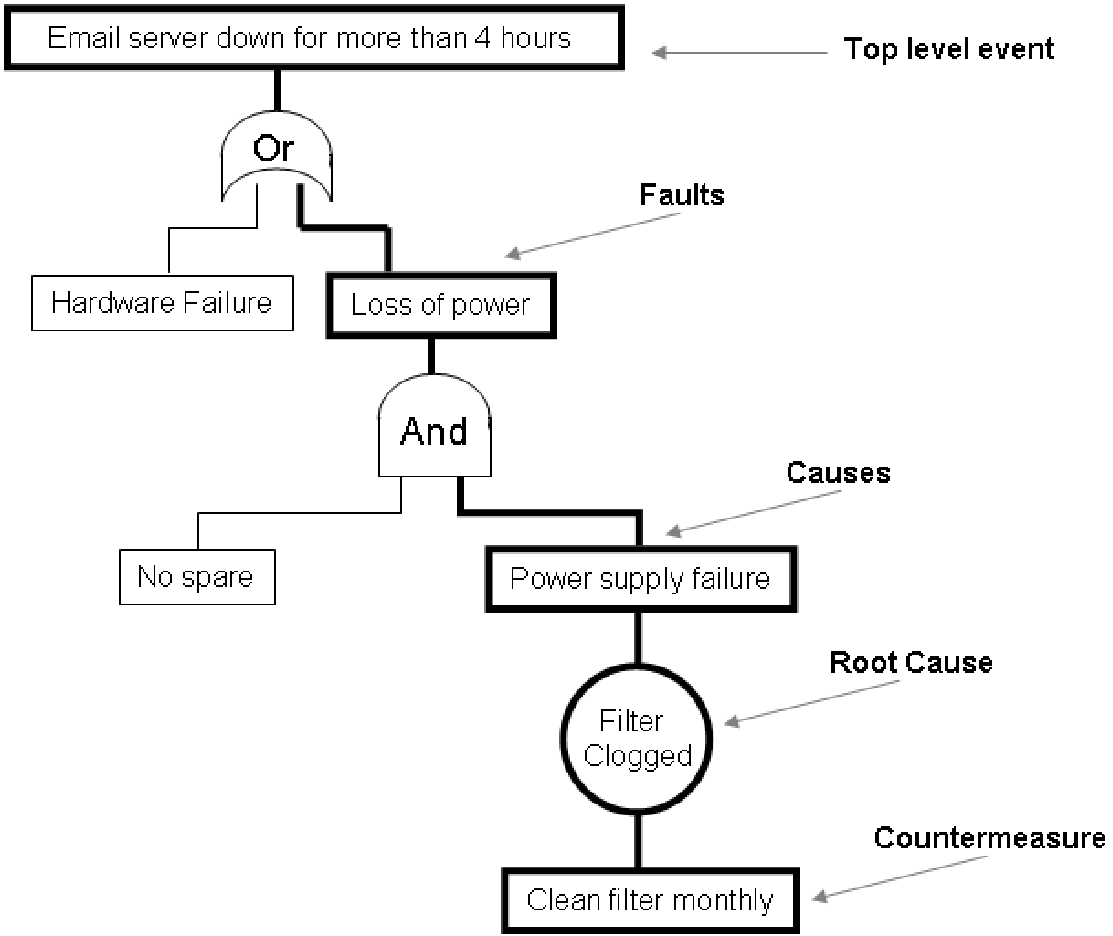


Input	Output
A	**C**
0	1
1	0

Fault Tree Analysis Explanation



Example Fault Tree Analysis



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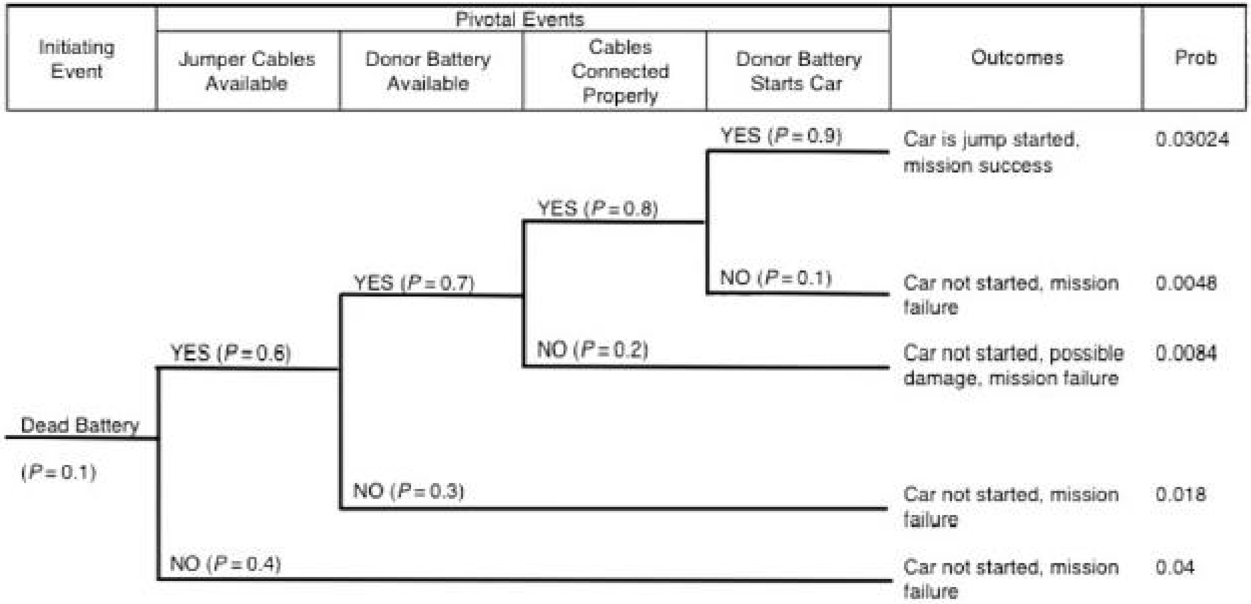
Event Tree Analysis

- Event tree analysis (ETA) is a forward, bottom up, logical modeling technique for both success and failure that explores responses through a single initiating event and lays a path for assessing probabilities of the outcomes and overall system analysis.
- This analysis technique is used to analyze the effects of functioning or failed systems given that an event has occurred.
- ETA is a powerful tool that will identify all consequences of a system that have a probability of occurring after an initiating event that can be applied to a wide range of systems.
- This Technique may be applied to a system early in the design process to identify potential issues that may arise rather than correcting the issues after they occur.
- ETA uses a type of modeling technique called event tree, which branches events from one single event using Boolean logic.

Event Tree Analysis



(C) Clifton et al.

5Whys Technique

- Controlled MOE copy in hangar is revision 11, current revision in library is 12. (the finding)
  - *Why?* – MOE revision 12 is not implemented in the hangar copy. (First why)
  - *Why?* – MOE revision 12 package was never received in the hangar. (Second why)
  - *Why?* – It got lost in company mail. (Third why)
  - *Why?* – Comail department does not have full traceability of shipments which makes lost mail possible. (Fourth why)
  - *Why?* – Company’s internal mail process does not require traceability of shipments. (Fifth why, a root cause)

5Whys Technique (cont'd)

- The questioning for this example could be taken further to a sixth, seventh, or higher level, but five iterations of asking why is generally sufficient to get to a root cause.
- Note that, in this example, the fifth why suggests a broken process or an alterable behavior, which is indicative of reaching the root-cause level.
- The *real* root cause should point toward a process that is not working well or does not exist.
- Untrained facilitators will often observe that answers seem to point towards classical answers such as not enough time, not enough investments, or not enough manpower. These answers may be true, but they are out of our control. Therefore, instead of asking the question „why?", ask „why did the process fail?"
- A key phrase to keep in mind in any 5 Why exercise is "people do not fail, processes do".

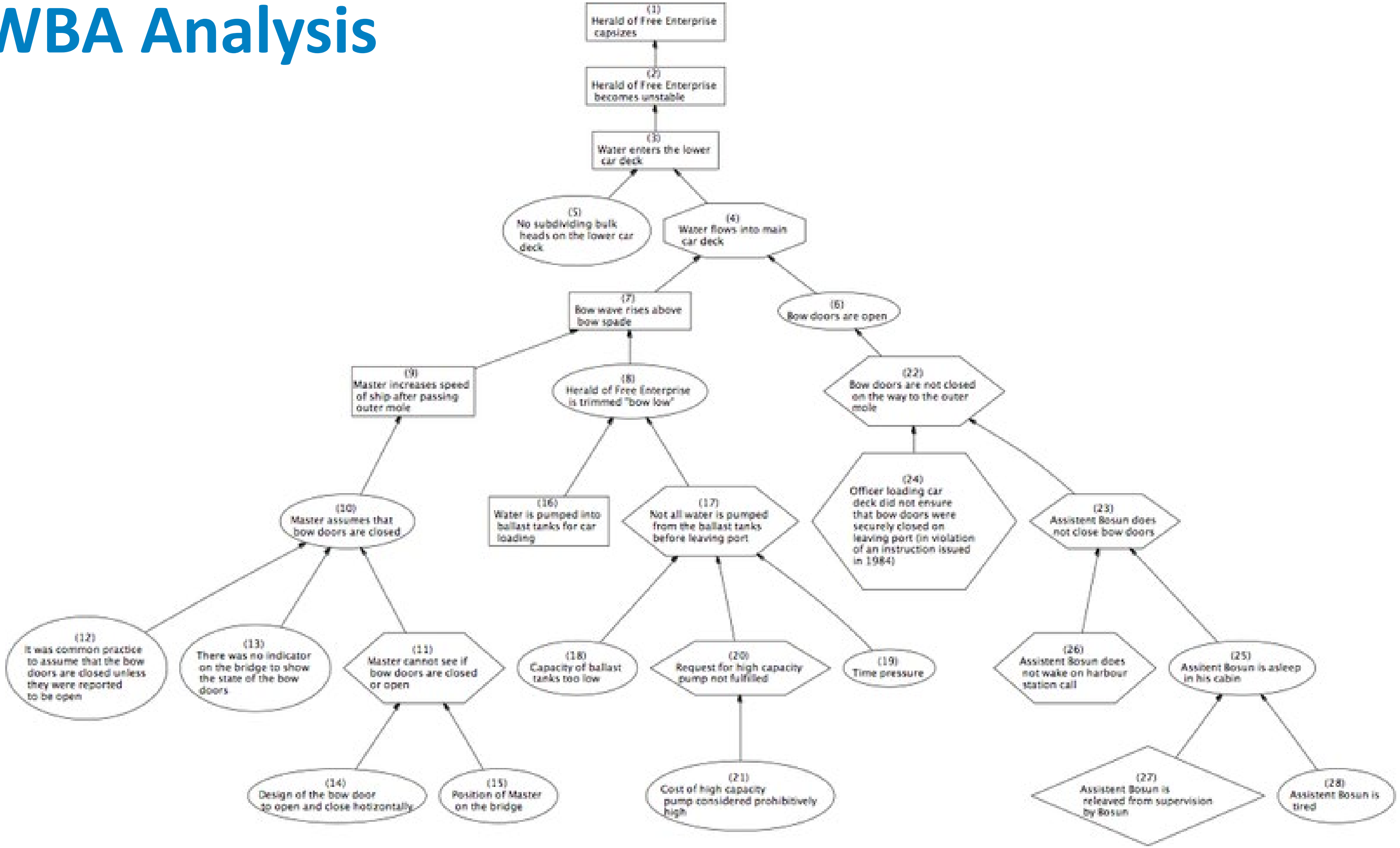
Some Rules in Performing 5Whys

- For the analysis itself, the right working group with facilitator should be formed.
- Paper or whiteboard should be used instead of computers.
- It has to be verified that root causes certainly lead to the mistake by reversing the sentences created as a result of the analysis with the use of the expression “and therefore”.
- Root cause should be reached step by step. Don’t jump to conclusions.
- Never leave “human error”, “worker’s inattention”, etc., as the root cause.
- Foster an atmosphere of trust and sincerity.
- Ask the question “Why” until the root cause is determined, i.e. the cause the elimination of which will prevent the error from occurring again.

Why-Because Analysis

- WBA starts with the question "What is the problem or problems in question?".
- Next comes an iterative process to determine causes.
- When causes for the accident have been identified, formal tests are applied to all potential cause-effect relations.
- At each node (factor), each contributing cause (related factor) must have been necessary to cause the accident, and the totality of causes must have been sufficient to do so.

Example WBA Analysis



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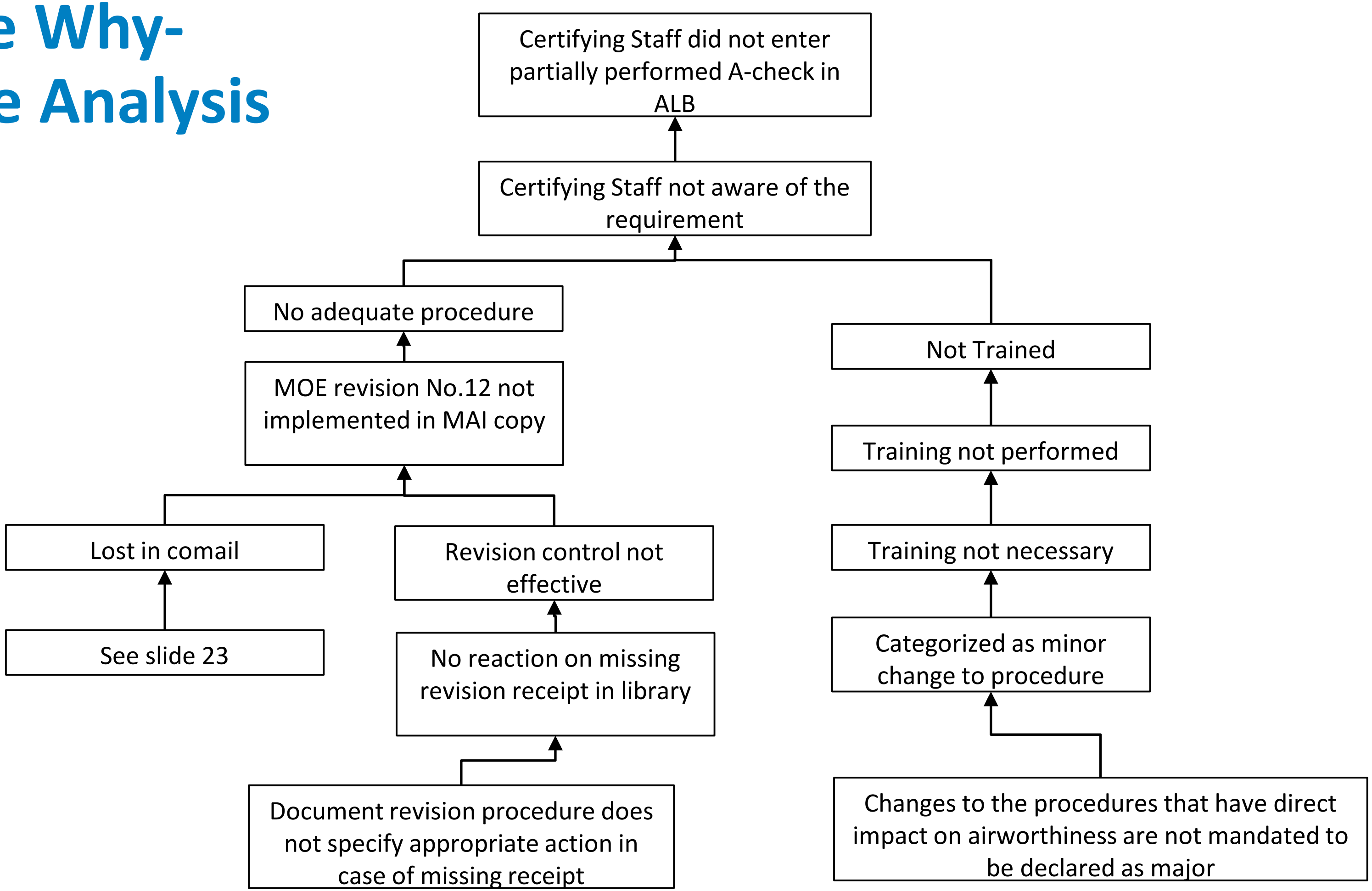
Exercise

- Problem:
  After performed one part of A-check (43 tasks out of total 89), aircraft was released to service. In Aircraft Log Book, work performed was not mentioned nor referred to and CRS was released.
- Certifying staff in charge said in the interview that they were not aware that there is a requirement to enter data about the work performed on partial A check into ALB. Normally, they said, data are entered in ALB and work is certified after the check is completed fully on the next day.

Exercise cont'd

- There was Revision No. 12 of the MOE which was introducing the procedure of issuing CRS after incomplete work, but revision was not implemented in controlled copy of MOE that is distributed in hangar.
- Reason for not revising the hangar copy of the MOE was the fact that revision package got lost somewhere in company mail, so hangar personnel was not aware of the revision and consequently they did not fill in revision receipt, which then never arrived in library who is in charge for revision control. Document revision procedure doesn't specify how to deal with revision receipts.
- Owner/author of the procedure considered this revision as minor change to the existing CRS procedure, so (in accordance with Documentation publication procedure) there was no obligation to perform any form of training of personnel.

Exercise Why-Because Analysis



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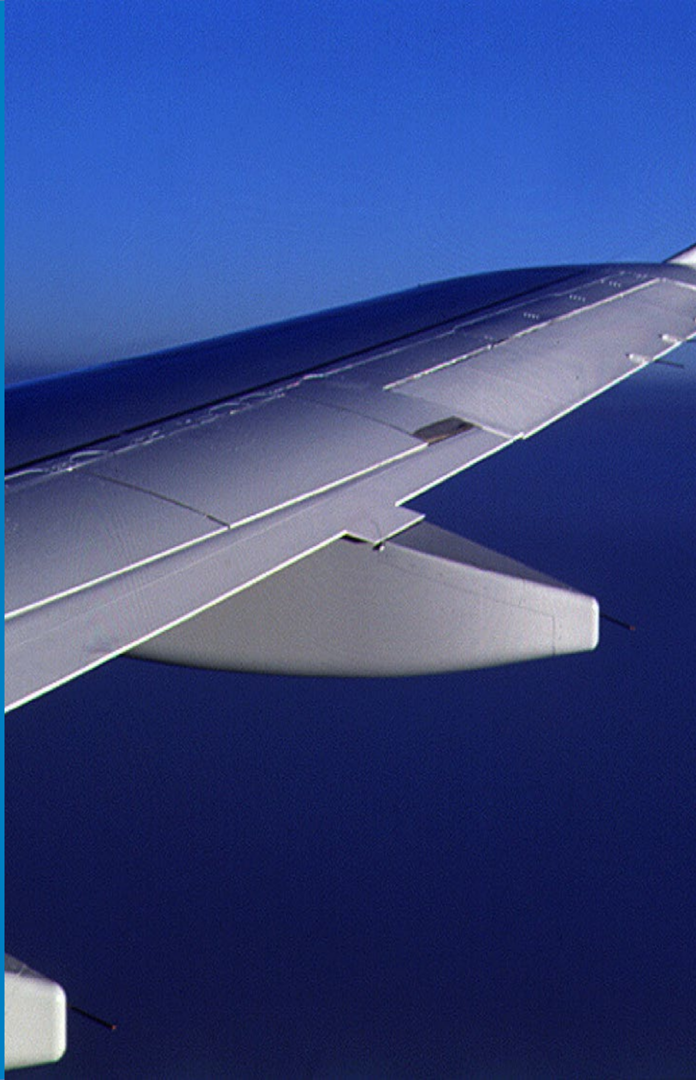
Corrective Action Definition



Purpose of Corrective Action

- Corrective action has two functions:
  - To remedy identified problem and
  - To remove weak points in the processes and procedures and thus improve them.
- It is a common misconception that the sole purpose of corrective action is to remedy existing finding and prevent the occurrence of the identified noncompliance in the future.
- Of course, corrective action should prevent such specific problem in the future, but this should come as a result of corrective action acting on the whole process which will be improved.
- There is an analogy which can be drawn between a human body and an organization. When we are sick, for example we have pneumonia, we may have symptoms like fever, coughing or pain. Doctors are always concentrated on curing our disease, not on single symptom. Thus, when we cure pneumonia, we have eliminated all the symptoms.

Corrective Action Definition

- Responsible manager is responsible for timely definition of appropriate corrective action.
- Intensity of a corrective action has to be proportional to the safety risks involved.
- Sometimes part of corrective action that remedies identified problem has to take place immediately and then the second part (improvement of the process) takes place on a longer timescale.
- Bearing in mind greater goals that we want to achieve (improvement of our processes), it is important to start the process of CA definition with root cause analysis of the finding.
- In most cases, performance of root cause analysis is not trivial task. It requires effort of an expert team sometimes with facilitator role.
- Once root cause (or root causes) are identified, most appropriate actions have to be defined to make process improvements.

Role of Quality Manager/Team Leader

- First priority of Quality Manager is that corrective actions are defined within reasonable period of time.
  - Often, responsible managers tend to delay definition of corrective actions. In such cases, Quality Manager should put continuous pressure on responsible managers to do their job and if this is not successful, ultimately report to Accountable manager.
- Once corrective action has been defined it has to be submitted to Quality Manager for review and approval.
- Quality Manager shall:
  - Review root cause analysis
  - Evaluate proposed corrective actions and deadlines, making sure that corrective actions are effective (not „cosmetic”) and that deadlines are realistic and proportional to the risks involved,
  - Approve corrective actions and enter them into the centralized monitoring system.

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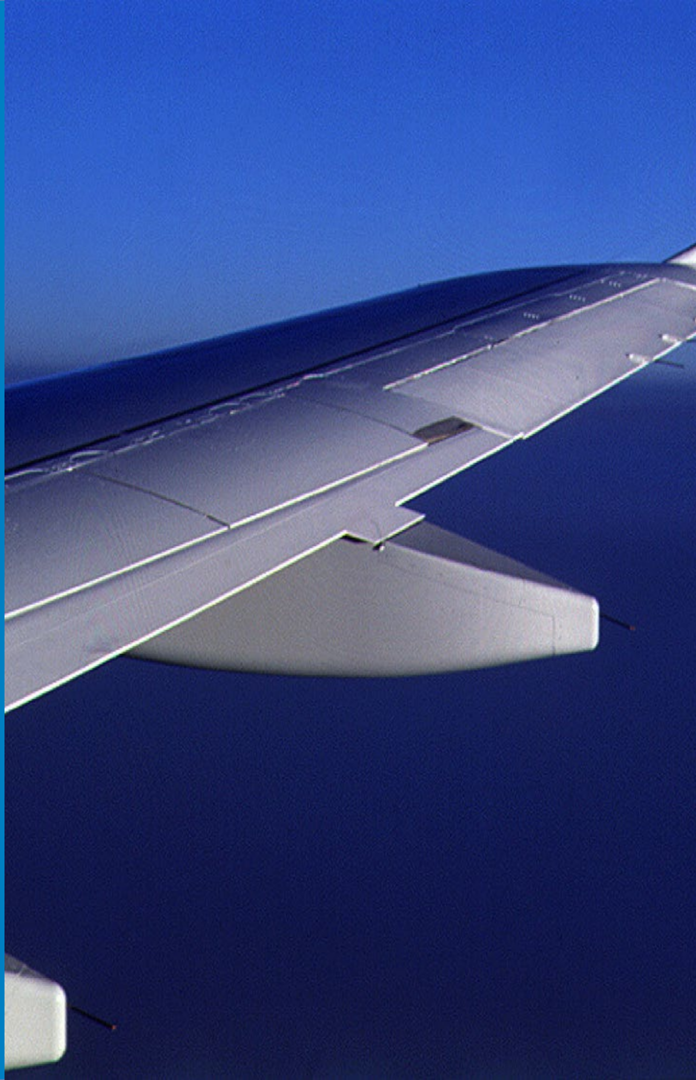
Follow up and closure of finding



Follow up

- Once Corrective Actions are approved, Responsible Manager should take necessary actions in order to implement Corrective Actions within approved deadlines.
- If during the course of action it becomes evident that deadlines are not possible to be met, he has to inform Quality Manager in written about the problem and ask for extension of deadline with appropriate explanation.
- Quality Manager shall evaluate request and decide whether extension is approved or not.
- If corrective action has more steps with check points in between the steps, RM will inform QM that certain part of corrective action is finished and ready for verification by the QM.
- Such verification shall be recorded in centralized database.

Follow up (cont'd)

- Once corrective action is completed, QM will be informed by RM and final verification will be done.
- Method used to verify effective performance of Corrective Action depends on the nature of CA. It can be:
  - Review of submitted documents (e.g.. Procedures, records...),
  - Inspection,
  - Follow up audit or
  - Any combination of above
- Once Corrective Action is verified, QM closes the finding

Long Term Effectiveness of Corrective Action

- Real effectiveness of Corrective Action in many situations can be determined only after longer period of time.
- Therefore, all findings from previous audit should be revisited on next audit to determine that then identified problem is permanently remedied.
- It is not rare that such follow up reveals that the problem remains. This is indication that:
  - corrective actions carried out were not appropriate or
  - were not adequately implemented
- One of the indicators of effectivity of the whole Compliance Monitoring program is the number of repetitive findings.

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Licencing of Certifying Staff
EASA Part 66

Omer Pita and Salvador Alepuz
Airworthiness Experts

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EASA Part 66 Licenses

- Aircraft maintenance licences include the following categories:
- Category A
- Category B1
- Category B2
- Category B3
- Category C

EASA Part 66 Licenses

- Categories A and B1 are subdivided into subcategories relative to combinations of aeroplanes, helicopters, turbine and piston engines. These subcategories are:
- A1 and B1.1 Aeroplanes Turbine
- A2 and B1.2 Aeroplanes Piston
- A3 and B1.3 Helicopters Turbine
- A4 and B1.4 Helicopters Piston
- Category B3 is applicable to piston-engine non-pressurised aeroplanes of 2000 kg MTOM and below.

Privileges

- Category A aircraft maintenance licence permits the holder to issue certificates of release to service following:
  - minor scheduled line maintenance and simple defect rectification within the limits of tasks specifically endorsed on the **Part-145 certification authorisation**
  - The certification privileges shall be restricted to work that the licence holder has personally performed in the maintenance organisation that issued the certification authorisation.

Privileges

- Category B1 aircraft maintenance licence shall permit the holder to issue certificates of release to service and to act as B1 support staff following:
  - maintenance performed on aircraft structure, powerplant and mechanical and electrical systems,
  - work on avionic systems requiring only simple tests to prove their serviceability and not requiring troubleshooting.
- Category B1 includes the corresponding A subcategory.

Privileges

- Category B2 aircraft maintenance licence shall permit the holder:
  - to issue certificates of release to service and to act as **B2 support staff** for following:
    - maintenance performed on avionic and electrical systems, and
    - electrical and avionics tasks within powerplant and mechanical systems, requiring only simple tests to prove their serviceability; and
  - to issue certificates of release to service following minor scheduled line maintenance and simple defect rectification within the limits of tasks specifically endorsed on the certification authorisation. This certification privilege shall be restricted to work that the licence holder has personally performed in the maintenance organisation which issued the certification authorisation and limited to the ratings already endorsed in the B2 licence.
- The category B2 licence does not include any A subcategory.

Privileges

- A category B3 aircraft maintenance licence shall permit the holder to issue certificates of release to service and to act as B3 support staff for:
  - maintenance performed on aeroplane structure, powerplant and mechanical and electrical systems,
  - work on avionic systems requiring only simple tests to prove their serviceability and not requiring troubleshooting.

- A category C aircraft maintenance licence shall permit the holder to issue certificates of release to service following **base maintenance** on aircraft. The privileges apply to the aircraft in its entirety.

Language proficiency (GM 66.A.20(b)4 Privileges)

- Holders of a Part-66 aircraft maintenance licence may not exercise certification privileges unless they have a general knowledge of the language used within the maintenance environment including knowledge of common aeronautical terms in the language. The level of knowledge should be such that the licence holder is able to:
  - read and understand the instructions and technical manuals used for the performance of maintenance;
  - make written technical entries and any maintenance documentation entries, which can be understood by those with whom they are normally required to communicate;
  - read and understand the maintenance organisation procedures;
  - communicate at such a level as to prevent any misunderstanding when exercising certification privileges.

66.A.30 Basic experience requirements

- for category A, subcategories B1.2 and B1.4 and category B3:
- 3 years of practical maintenance experience on operating aircraft, if the applicant has no previous relevant technical training; or
- 2 years of practical maintenance experience on operating aircraft and completion of training considered relevant by the competent authority as a skilled worker, in a technical trade; or
- 1 year of practical maintenance experience on operating aircraft and completion of a basic training course approved in accordance with Annex IV (Part-147);

66.A.30 Basic experience requirements

- for category B2 and subcategories B1.1 and B1.3:
- 5 years of practical maintenance experience on operating aircraft if the applicant has no previous relevant technical training; or
- 3 years of practical maintenance experience on operating aircraft and completion of training considered relevant by the competent authority as a skilled worker, in a technical trade; or
- 2 years of practical maintenance experience on operating aircraft and completion of a basic training course approved in accordance with Annex IV (Part-147);

66.A.30 Basic experience requirements

- for category C with respect to complex motor-powered aircraft:
- 3 years of experience exercising category B1.1, B1.3 or B2 privileges on complex motor-powered aircraft or as support staff according to point 145.A.35, or, a combination of both; or
- 5 years of experience exercising category B1.2 or B1.4 privileges on complex motor- powered aircraft or as support staff according to point 145.A.35, or a combination of both;
- For a category C applicant holding an academic degree the representative selection of tasks should include the observation of hangar maintenance, maintenance planning, quality assurance, record-keeping, approved spare parts control and engineering development.

Aircraft Ratings

Aircraft rating requirements			
Aircraft Groups	B1/B3 licence	B2 licence	C licence
Group1 - Complex motor-powered aircraft. - Multiple engine helicopters. - Aeroplanes certified above FL290. - Aircraft equipped with fly-by-wire. - Other aircraft when defined by the Agency.	(For B1) **Individual TYPE RATING** Type training: - Theory + examination - Practical + assessment **PLUS** OJT (for first aircraft in licence subcategory)	**Individual TYPE RATING** Type training: - Theory + examination - Practical + assessment **PLUS** OJT (for first aircraft in licence subcategory)	**Individual TYPE RATING** Type training: - Theory + examination
Group 2 Subgroups: 2a: single turboprop aeroplanes (*) 2b: single turbine engine helicopters (*) 2c: single piston engine helicopters (*) (*) Except those classified in Group 1.	(For B1.1, B1.3, B1.4) **Individual TYPE RATING** (type training + OJT) **or** (type examination + practical experience) **Full SUBGROUP RATING** (type training + OJT) **or** (type examination + practical experience) on at least 3 aircraft representative of that subgroup **Manufacturer SUBGROUP RATING** (type training + OJT) **or** (type examination + practical experience) on at least 2 aircraft representative of that manufacturer subgroup	**Individual TYPE RATING** (type training + OJT) **or** (type examination + practical experience) **Full SUBGROUP RATING** based on demonstration of practical experience **Manufacturer SUBGROUP RATING** based on demonstration of practical experience	**Individual TYPE RATING** type training **or** type examination **Full SUBGROUP RATING** type training **or** type examination on at least 3 aircraft representative of that subgroup **Manufacturer SUBGROUP RATING** type training **or** type examination on at least 2 aircraft representative of that manufacturer subgroup

Aircraft Ratings

Aircraft rating requirements			
Aircraft Groups	B1/B3 licence	B2 licence	C licence
Group3 Piston engine aeroplanes (except those classified in Group 1)	(For B1.2) **Individual TYPE RATING** (type training + OJT) **or** (type examination + practical experience) **Full GROUP 3 RATING** based on demonstration of practical experience **Limitations:** - Pressurized aeroplanes - Metal aeroplanes - Composite aeroplanes - Wooden aeroplanes - Metal tubing & fabric Aeroplanes	**Individual TYPE RATING** (type training + OJT) **or** (type examination + practical experience) **Full GROUP 3 RATING** based on demonstration of appropriate experience	**Individual TYPE RATING** type training **or** type examination **Full GROUP 3 RATING** based on demonstration of practical experience
Piston-engine non-pressurized aeroplanes of 2 000 kg MTOM and below	(For B3) **FULL RATING "Piston-engine non-pressurized aeroplanes of 2 000 kg MTOM and below"** based on demonstration of practical experience **Limitations:** - Metal aeroplanes - Composite aeroplanes - Wooden aeroplanes - Metal tubing & fabric aeroplanes	**Not applicable**	**Not applicable**

EASA

→ Link To EASA Part 66

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Quality Assurance/Compliance Monitoring Program

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Airworthiness Experts

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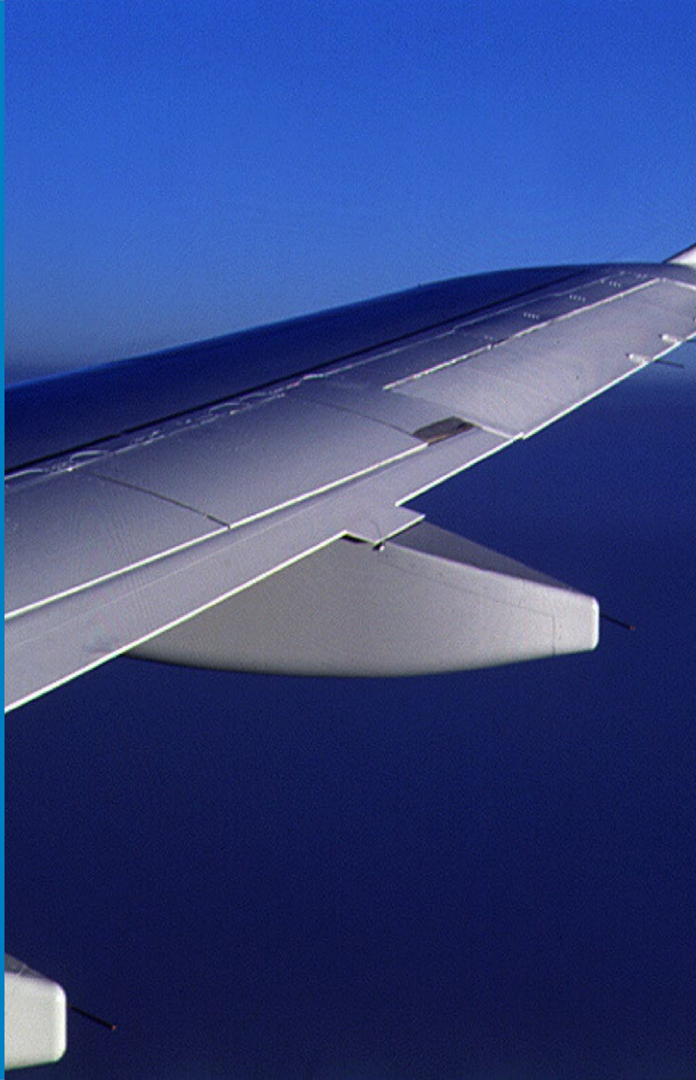
Definitions



ISO 19011:2011 Definitions

- Audit:
  systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
  - Internal audits, sometimes called first party audits, are conducted by the organization itself, or on its behalf, for management review and other internal purposes
  - External audits include second and third party audits.
    - Second party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf.
    - Third party audits are conducted by independent auditing organizations, such as regulators or those providing certification.
  - When two or more management systems of different disciplines (e.g. quality, environmental, occupational health and safety) are audited together, this is termed a combined audit.
  - When two or more auditing organizations cooperate to audit a single auditee, this is termed a joint audit.)

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ISO 19011:2011 Definitions

- **Audit criteria**:
  set of policies, procedures or requirements used as a reference against which audit evidence is compared.
  - If the audit criteria are legal (including statutory or regulatory) requirements, the terms “compliant” or “non-compliant” are often used in an audit finding.
- **Audit evidence:**
  records, statements of fact or other information which are relevant to the audit criteria and verifiable.

ISO 19011:2011 Definitions

- Audit findings:
  results of the evaluation of the collected audit evidence against audit criteria
  - Audit findings indicate conformity or nonconformity.
  - Audit findings can lead to the identification of opportunities for improvement or recording good practices.
  - If the audit criteria are selected from legal or other requirements, the audit finding is termed compliance or non-compliance.

ISO 19011:2011 Definitions

- **Auditee:** organization being audited
- **Auditor:** person who conducts an audit
- **Audit team:** one or more auditors conducting an audit, supported if needed by technical experts
  - One auditor of the audit team is appointed as the audit team leader.
  - The audit team may include auditors-in-training.

ISO 19011:2011 Definitions

- **Technical expert**: person who provides specific knowledge or expertise to the audit team
  - Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or language or culture.
  - A technical expert does not act as an auditor (3.8) in the audit team.

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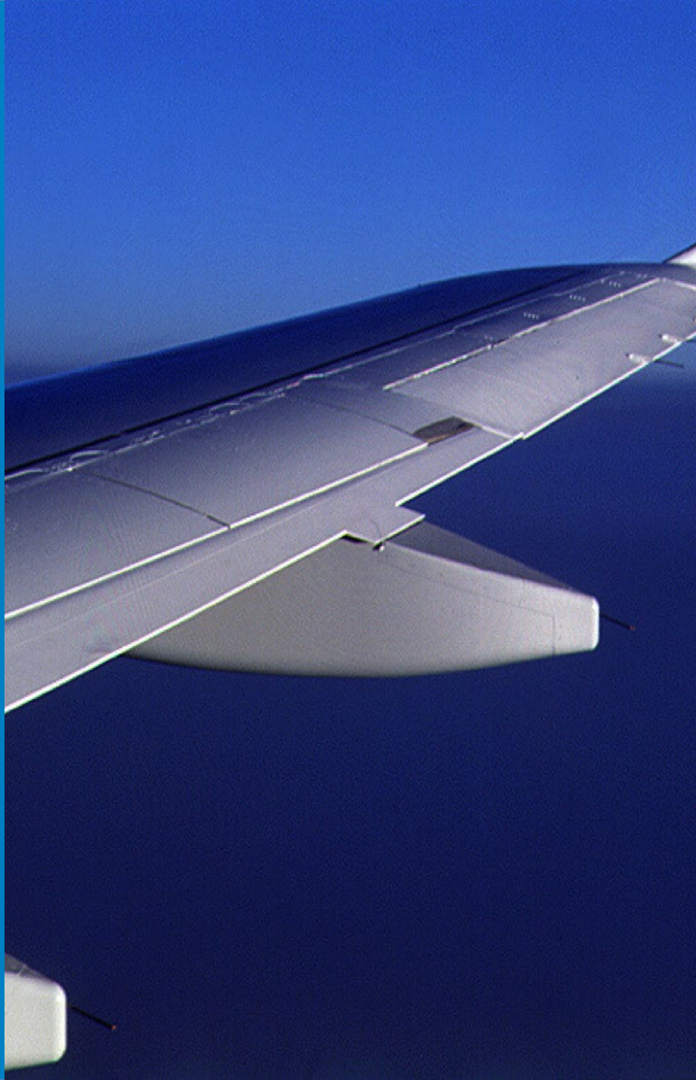
Requirements for the establishment of the Compliance Monitoring Program



An Agency of the European Union

Audit Program/Compliance Monitoring Program

- Terms Audit Program, Quality Assurance Program and Compliance Monitoring Program are frequently used interchangeably and often mean the same.
- Quality Assurance Program or Compliance Monitoring Program tend to be wider terms than Audit Program and comprise of:
  - Audit Program (ISO9001 Chapter 9.2)
  - Audit (ISO9001 Chapter 9.2)
  - Analysis of findings (ISO9001 Chapter 10.2)
  - Corrective action procedure (ISO9001 Chapter 10.2)

9.2 Internal Audit in ISO9001:2015

- 9.2.2 The organization shall:
  - plan, establish, implement and maintain an Audit Program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - define the audit criteria and scope for each audit;

9.2 Internal Audit in ISO9001:2015

- select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- ensure that the results of the audits are reported to relevant management;
- take appropriate correction and corrective actions without undue delay;
- retain documented information as evidence of the implementation of the Audit Program and the audit results

Compliance Monitoring in EU Air OPS

→ORO.GEN.200 Management system:

a) The operator shall establish, implement and maintain a management system that includes:

   6) a function to monitor compliance of the operator with the relevant requirements.
   Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary;

Compliance Monitoring in EU Air OPS

→AMC1 ORO.GEN.200(a)(6) Management system:

c) Organizational set up

2) The compliance monitoring manager should be responsible for ensuring that the compliance monitoring program is properly implemented, maintained and continually reviewed and improved.

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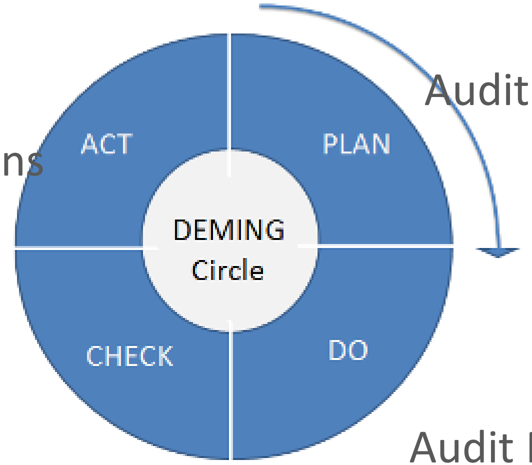
Compliance Monitoring Program

From the point of view of the all Organisation’s processes:

Perform
Corrective Actions

Audit program



Analysis,
Risk Assesment,
Root Cause,
Define Corrective Action

Audit Performance

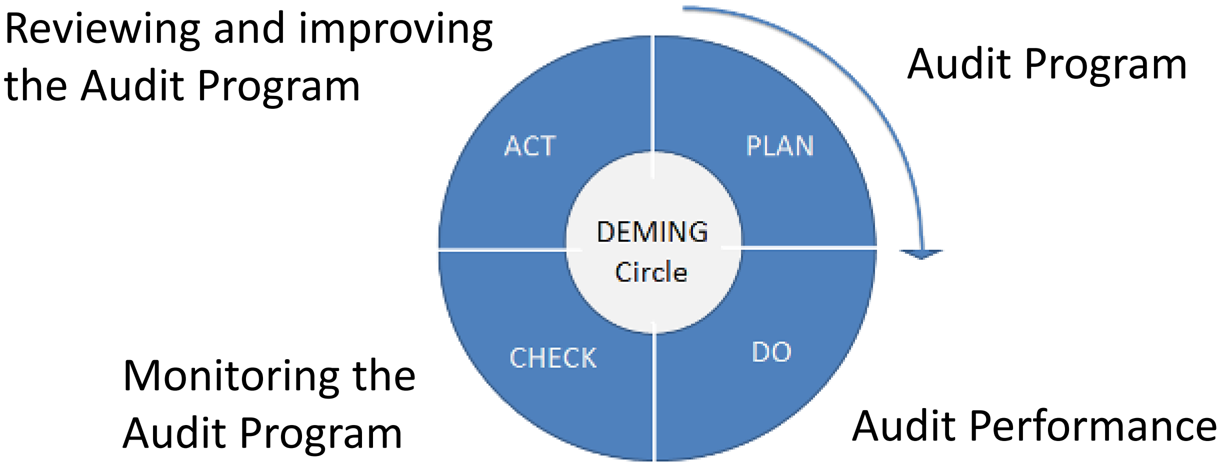
This is how Compliance Monitoring Program affects and improves whole Organisation

Compliance Monitoring Program (cont'd)

- So main elements of Compliance Monitoring Program are:
  - Audit Program
  - Audit
  - Analysis and definition of corrective actions
  - Performance and verification of performed corrective actions
- Compliance Monitoring Program must ensure that Organization improves continuously.
- Performing audit alone does not produce any positive effect unless it is followed by effective corrective actions.

Compliance Monitoring Program (cont'd)

From the point of view of the Compliance Monitoring Function alone (as required by ISO 19011:2011 and eg. EU Air OPS):

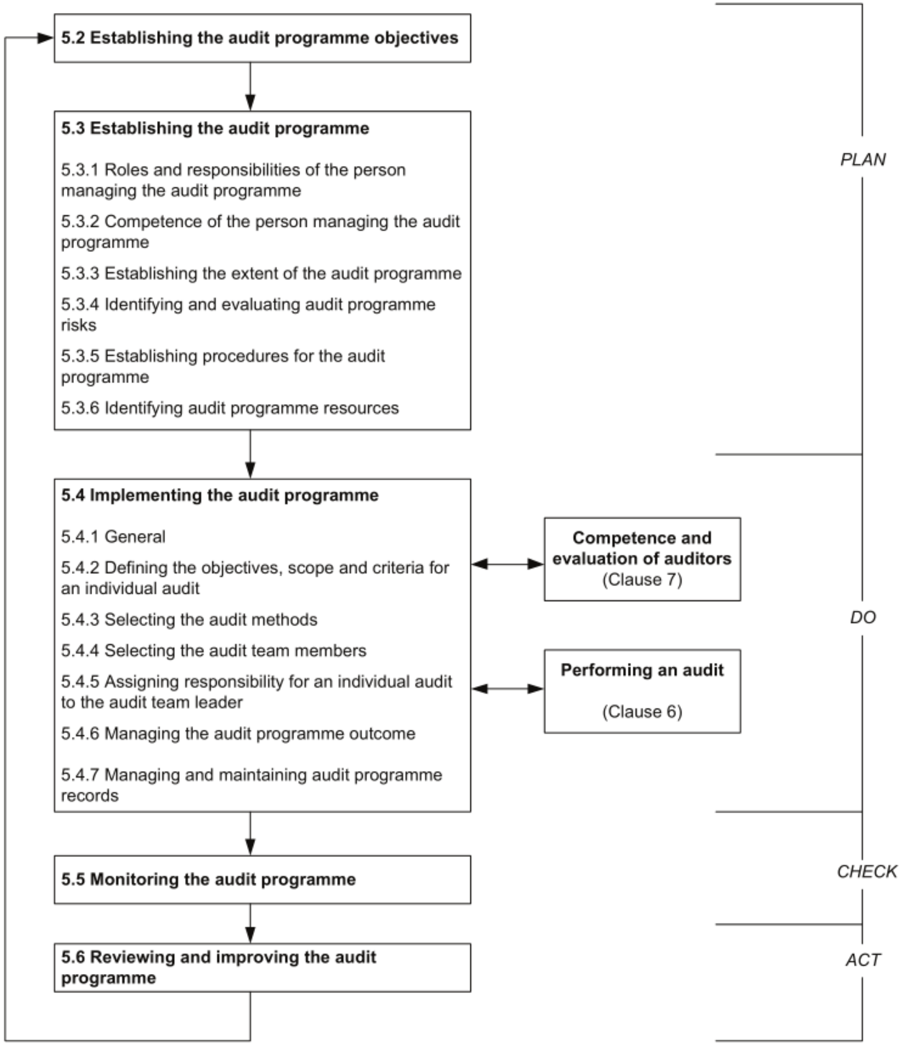


This is how Compliance Monitoring Program affects and improves itself

Compliance Monitoring Program (cont'd)

- Compliance monitoring function has to continuously improve itself.
- Therefore, there are additional elements of CMP that have to be built into Audit Program:
  - Monitoring of Audit Program
  - Reviewing and improving of Audit Program
- Audit Program which does not change, very soon becomes ineffective.

ISO 19011:2011 take on Improvement of Audit Program



Establishment of Compliance Monitoring Program

- Compliance Monitoring Program (Quality Assurance Program) consists of following key elements:
  - Audit Program (Including Audit Schedule)
  - Performance of Audit
  - Analysis of findings
  - Corrective action procedure
  - Follow up
  - Reporting

Audit Program

- Audit Program
  - Audit program objectives;
  - The scope of the Audit Program;
  - Audit program schedule;
  - Audit program responsibilities;
  - Organizational procedures for audit performance;
  - Auditor competence standards and evaluation of auditors;
  - Necessary resources;
  - Reporting and communicating of the Audit results;
  - Management of Audit Records;
  - Continuous monitoring, review and improvement of the Audit Program

Audit Program Objectives

- It is task of top management to set objectives for audit program
- Objectives can be set based on:
  - Regulatory requirements (requiring Audit Program to ensure compliance with certain regulation)
  - Decision of management to comply with voluntary standards like ISO9001
  - Level of maturity of management system
  - Results of previous audits, risk analysis of the findings, negative trends
  - Management priorities
- In aviation objectives are „predetermined” with applicable regulatory requirements, but still can be designed to address other priorities on top of regulatory minimum

Audit Program Objectives

- Example Audit Program Objectives:
- *Objectives of XYZ company's Audit Program are:*
  - *To establish and monitor compliance of XYZ company with*
    - *EASA Part 145 regulations,*
    - *EASA Part M*
    - *EASA Air OPS,*
    - *XYZ approved Manuals (CAME, MOE, OM…)*
  - *To assure compliance by intensified monitoring in OPS Department based on risk assessment of audit results from previous year*
  - *To verify regulatory compliance of organizational changes in Maintenance Department planned in second half of the year*

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The Scope of the Audit Program

AUDIT AREA		INTERVAL MONTHS	V/P M&E			QA	TSE					MAI				
MOE chap.	DESCRIPTION			TA	CC		DIR	ENG	PPC	MAT	LOG	DIR	MEN	MTI	LAM	BAM
	MAINTENANCE PROCEDURES															
2.1	Supplier evaluation procedure	24				❖				❖						
2.2	Acceptance of components & materiel from outside sources	12								❖						
2.3	Storage / tagging release	12								❖						
n.a.	Special material arrangments, pooling of parts	12								❖						
n.a.	Purchasing	12								❖						
2.4	Acceptance of tools and equipment in use	24								❖						
2.5	Calibration of tool and equipment (in storage)	12							❖							
2.6	Use of tooling and equipment by the staff	24							❖	❖				❖	❖	❖
2.7	Cleanliness standards	24				❖	❖	❖	❖	❖	❖	❖	❖	❖	❖	❖
2.8	Maintenance instructions updating	12						❖				❖	❖	❖	❖	❖
2.9	Repair procedures	24						❖	❖				❖	❖	❖	❖
2.10	A/C Maintenance Program compliance	24						❖	❖							
2.11	Airworthiness directive procedure	24						❖								
2.12	Optional modification procedure	24						❖								

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Audit Program Schedule

AUDIT AREA		INTERVAL MONTHS	V/P M&E			QA	TSE					MAI				
MOE chap.	DESCRIPTION			TA	CC		HEAD	ENG	PPC	MAT	LOG	HEAD	MCC	QC	LINE	BASE
2.1	Supplier evaluation procedure	24				02.05				05.05						
2.2	Acceptance of components & materiel from outside sources	12								05.05						
2.3	Storage / tagging release	12								05.05						
n.a.	Special material arrangments, pooling of parts	12								05.05						
n.a.	Purchasing	12								05.05						
2.4	Acceptance of tools and equipment in use	24								05.05						
2.5	Calibration of tool and equipment (in storage)	12							04.05							
2.6	Use of tooling and equipment by the staff	24							04.05	05.05				10.05	11.05	12.05
2.7	Cleanliness standards	24				02.05	03.05	03.05	04.05	05.05	08.05	09.05	09.05	10.05	11.05	12.05
2.8	Maintenance instructions updating	12						03.05				09.05	09.05	10.05	11.05	12.05
2.9	Repair procedures	24						03.05	04.05				09.05	10.05	11.05	12.05
2.10	A/C Maintenance Program compliance	24						03.05	04.05							
2.11	Airworthiness directive procedure	24						03.05								
2.12	Optional modification procedure	24						03.05								
2.13	Maintenance documentation issue and use	24						03.05	04.05				09.05	10.05	11.05	12.05
2.14	Technical Records Control	24							04.05							

Schedule of Vendor Audits

Vendor code	Vendor	Date	Duration	Ref. Standard
NAYAK	NAYAK AIRCRAFT SERVICE GmbH	12.09.17	1 day	Part145
NL198	HAMILTON STANDARD, Customer Support Center Maastricht	10.10.17	1 day	Part145
64	SECA Groupe Aerospatiale Le Bourget	17.10.17	2 days	Part145
LHTWE	LUFTHANSA TECHNIK Customer Services Engine Maintenance Hamburg	07.11.17	2 days	Part145
LHTWA	LUFTHANSA TECHNIK Customer Aircraft Maintenance Frankfurt	19.12.17	3 days	Part145

Audit Program Responsibilities

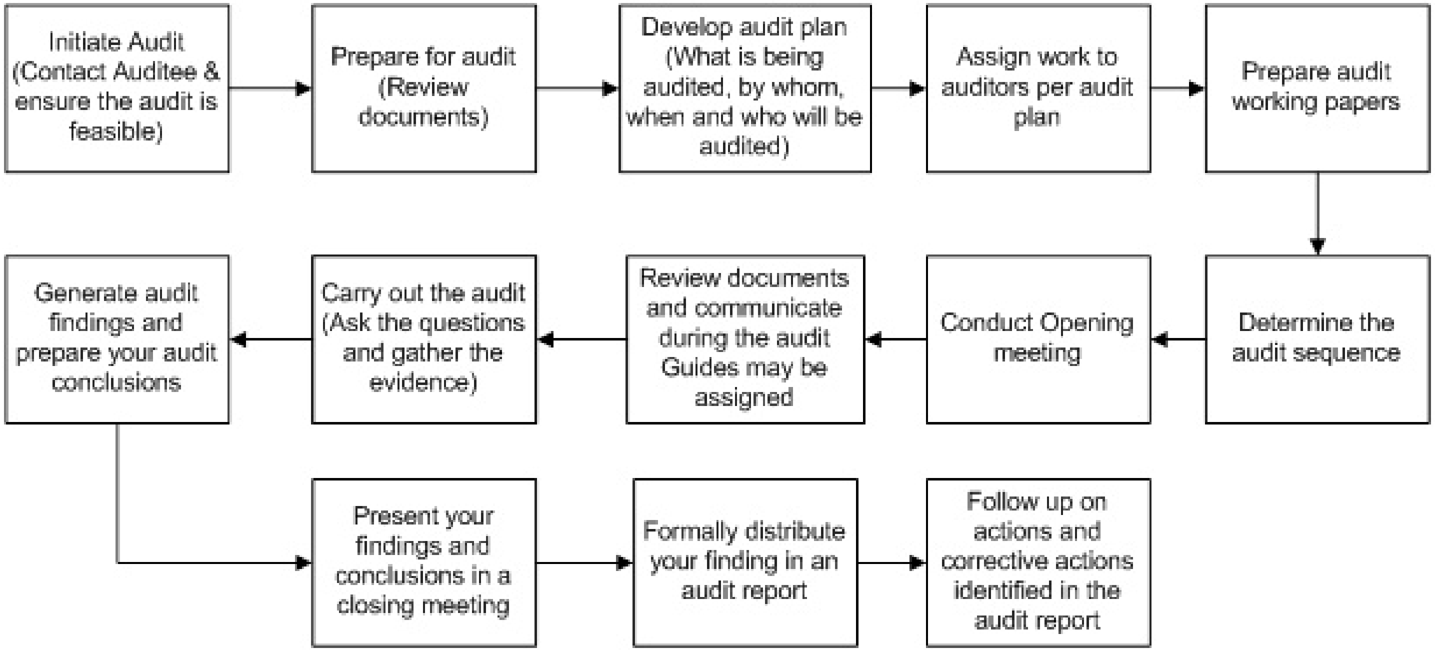
„Leave responsibility where it belongs.”

- Each Audit Program has to have defined responsibilities as follows:
  - Quality Manager role and responsibilities
  - Role and responsibility of top level of management (CEO, Sector Directors)
  - *Other roles and responsibilities that are essential to full functionality of Audit Program (if existing)*

Organizational Procedures for Audit Performance

- One or more procedures should be established, addressing the following, as applicable:
  - planning and scheduling of audits;
  - ensuring information security and confidentiality;
  - assuring the competence of auditors and audit team leaders;
  - selecting appropriate audit teams and assigning their roles and responsibilities;
  - conducting audits, including the use of appropriate sampling methods;
  - conducting audit follow-up;
  - reporting to the top management on the overall results of the audit program;
  - maintaining audit program records;
  - monitoring and reviewing the performance and risks, and improving the effectiveness of the audit program.

Organizational Procedures for Audit Performance (cont'd)



Organizational Procedures for Audit Performance (cont'd)

RESPONSIBILITY / ACTIVITY	AM	QM	LA	AT	RM
Creation of Audit Programme		R			
Authorization of Audit Programme	R				
Audit Planning		R			
Release of Audit Order - OB-QMS-006/0		R			A
Performance of Internal Audit			R	R	
Creation of Audit Report and recording of non-compliances in the IT system			R	R	
Analysis of noncompliances, verification of the recorded dana and sending Audit Report - OB-QMS-004/0 to the Responsible Manager		R			
Conclusion of Internal Audit		R			

Legend:

AM Accountable Manager
QM Quality Manager
LA Lead auditor
AT Audit team member
RM Responsible Manager – superior of audited department mentioned in audit order
R Responsible
A Agrees with the contents of audit order and choice of auditors

Necessary Resources

- Audit Program should present and make sure that planned activities within the Audit Program are adequately supported by available resources:
  - Adequate number of available Auditors man-hours or man-days for carrying out the planned audits
  - Adequate specialties of available Auditors to cover whole scope of planned audits

Necessary Resources

- Adequate number of other Audit Program supporting staff (in case of large organizations)
- Adequate equipment (means of transport, IT equipment and software…)

Audit Program has its costs in terms of involved resources. It should be optimized to achieve optimal results with minimized costs.

Reporting and Communicating of Audit Program Results

- There are three ways of communicating Audit Program results:
  - Following each performed Audit, distribution of audit reports to responsible managers
  - Regular distribution of status reports of open findings to responsible managers and accountable manager
    - Should be done at least monthly
    - Should make each responsible manager aware of all open findings status in relation to corresponding corrective actions
  - Management Review should take place at least twice a year (regulatory requirement)
    - More detailed status followed by adequate analysis of data should be reported to the accountable manager and responsible managers

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Example of Regular Reporting

CROATIA AIRLINES
Technical Services
Quality Assurance

Open Irregularity Reports Status

Organization: **CTN**

Responsible Manager: **Vlašić**

IR No	Date	IR Reference	Priority	Due at	Responsible Dept. Manager:	Responsible Person:	Department Name:	Corrective action date
05009/00	04.05.2000	TS AUDIT 2000	2	01.01.2001	Alerić		Tech. Services	03.10.2000

NonCompliance: Resource planning - there is no written procedure dealing with manpower planning.
Recommendation: In addition to the planning procedure required by IR No. 08241/00, define procedure for manpower planning. Procedure to be included in TPM.
Corrective Action: See recommendation.

IR No	Date	IR Reference	Priority	Due at	Responsible Dept. Manager:	Responsible Person:	Department Name:	Corrective action date
05021/00	09.05.2000	TS AUDIT 2000	2	01.12.2000	Horvat		Tech. Services	03.10.2000

NonCompliance: It is not confirmed that there is procedure for AOG parts acquisition existing. Same procedure can not be found by MEN personnel
Recommendation: It is confirmed that no specific AOG parts acquiry procedure exists. Procedure should be written in MAT.
Corrective Action: See above recommendation.
Written procedure has to cover following:
- selection of supplier,
- control of shipping process,
- customs specific procedure

IR No	Date	IR Reference	Priority	Due at	Responsible Dept. Manager:	Responsible Person:	Department Name:	Corrective action date
05037/00	23.08.1999	KLM CS AUDIT	3	01.01.2001	Horvat		Tech. Services	07.09.2000

NonCompliance: Scrap procedure not established. Ref: FAA AC 21-38
Recommendation: Define scrap procedure in compliance with referenced standard. Introduce this procedure in MAT manual
Corrective Action: See recommendation

IR No	Date	IR Reference	Priority	Due at	Responsible Dept. Manager:	Responsible Person:	Department Name:	Corrective action date
08241/00	24.08.2000	Inv. Rept 000824	2	01.11.2000	Alerić		Tech. Services	28.08.2000

NonCompliance: No safety margin built in maintenance plan, no written planning procedure, no adequate plan follow up procedure.
Recommendation: Write maintenance planning procedure including: workflow, documentation, responsibilities, safety margins and plan verification. Procedure to be included in TPM
Corrective Action: See Recommendation

IR No	Date	IR Reference	Priority	Due at	Responsible Dept. Manager:	Responsible Person:	Department Name:	Corrective action date
08244/00	24.08.2000	Inv. Rept 000824	3	01.12.2000	Alerić		Tech. Services	28.08.2000

NonCompliance: Maintenance Plans created in AMICOS II are containing mixture of letter tasks (A, C) and CMRs with intervals defined in FH. This causes problems when doing time escalations (CMR tasks, in general, are not allowed to be escalated).
Recommendation: Extract all CMR tasks out from all existing AMICOS maintenance plans, to prevent possible confusion and errors in planning
Corrective Action: See recommendation

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Management of Audit Records

- Audit Program should ensure that audit records are created, managed and maintained to demonstrate the implementation of the audit program.
- Records should include the following:
  - records related to the audit program;
  - records related to each individual audit;
  - records related to audit personnel.
- The form and level of detail of the records should demonstrate that the objectives of the audit program have been achieved.

Management of Audit Records

- Minimum records that should be established and maintained are:
  - Audit Program Objectives
  - Audit Program Schedules and Plans
  - Audit Orders
  - *Audit Reports*
  - *Check Lists used on audit*
  - *Audit Evidences collected on audit*
  - *Follow up documents*
  - Auditor’s personal files

For each performed audit

Sample Audit Order

AUDIT ORDER

QUALITY DEPARTMENT

AUDIT ORDER No:	18/2016
AUDIT TYPE:	
SCHEDULED DATE OF AUDIT:	17. - 19.11.2016
AUDITEE:	AMC-Engineering department
RESPONSIBLE MANAGER:	Daniel Fong
AUDIT TEAM:	
Lead auditor:	Omer Pita
Auditor:	Denis Budimir, Daniela Mayer
Expert:	Mehmed Hasanović
Observer:	

AUDIT SCOPE	
CAME 3.1	A/C Tech log utilization and MEL application
CAME 3.2	A/C maintenance program development & amendment
CAME 3.3	Time and maintenance records: responsibility, retention, access...
CAME 3.4	Accomplishment and control of AD's

RELEVANT DOCUMENTS

CAME, REV.12/20.12.2016
EASA Part M
Check List: IO-3145-ENG
Audit report from previous audit

ADDITIONAL REMARKS

Any additional information that has relevance to the performance of the audit. It can be:

- Special arrangements or constraints for performance of audit (like …has to finish by 17:00 hours)
- Indication of focus points that need to be checked in more depth
- Additional information on audit team coordination

Issued by:	Name and Surname	Date:	Signature:
Quality Manager:			

Distributed to:	Lead auditor		
	Auditors		
	Responsible Manager		

Sample Audit Order Details

	AUDIT ORDER QUALITY DEPARTMENT
AUDIT ORDER No:	18/2016
AUDIT TYPE:	
SCHEDULED DATE OF AUDIT:	17. - 19.11.2016
AUDITEE:	AMC-Engineering department
RESPONSIBLE MANAGER:	Daniel Fong
AUDIT TEAM:	
Lead auditor:	Omer Pita
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Expert:	Mehmed Hasanović
Observer:	

AUDIT SCOPE	
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Sample Audit Order Details (cont'd)

RELEVANT DOCUMENTS
CAME, REV.12/20.12.2016 EASA Part M Check List: IO-3145-ENG Audit report from previous audit

ADDITIONAL REMARKS
Any additional information that has relevance to the performance of the audit. It can be: - Special arrangements or constraints for performance of audit (like …has to finish by 17:00 hours) - Indication of focus points that need to be checked in more depth - Additional information on audit team coordination

Issued by:	Name and Surname	Date:	Signature:
Quality Manager:			

Distributed to:	Lead auditor		
	Auditors		
	Responsible Manager		

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Sample Audit Report

AUDIT REPORT

QUALITY DEPARTMENT

AUDIT ORDER No:	18/2016
AUDIT DATES:	17. - 19.11.2016
AUDITEE:	AMC-Engineering department
RESPONSIBLE MANAGER:	Daniel Fong
AUDITED PERSONS:	Didier Bousquet, Stephen Martin, Ivana Horvat
AUDIT TEAM:	
Lead auditor:	Omer Pita
Auditor:	Denis Budimir, Daniela Mayer
Expert:	Mehmed Hasanović
Observer:	

INTRODUCTION

Here is the place for general description of the audit event, how was the audit carried out, level of communication and cooperation with auditee, positive findings or strong points of auditee discovered during the audit.

LIST OF NON-COMPLANCES

No.	Reference:	Non-Compliance	Level
1.	Regulation requirement or internal standard reference	Description of finding	
2.			
3.			

RECOMMENDATIONS AND CONCLUSION

Recommendations for the overall improvement of Audit process and/or
any additional information that Audit Team needs to communicate in relation to particular audit.

Developed by	Name and Surname	Date:	Signature:
Audit Team Leader	Omer Pita	20.11.2016	
Auditor:	Denis Budimir	20.11.2016	
Auditor:	Daniela Mayer	20.11.2016	
Auditor:			
Expert:	Mehmed Hasanović	20.11.2016	
Quality Manager Endorsement:			

Distributed to:	Responsible Manager		
	Sector Director		

Sample Audit Report - details

AUDIT REPORT

QUALITY DEPARTMENT

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AUDIT DATES:	17. - 19.11.2016
AUDITEE:	AMC-Engineering department
RESPONSIBLE MANAGER:	Daniel Fong
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Sample Audit Report – details (cont'd)

LIST OF NON-COMPLANCES			
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Auditor:	Daniela Mayer	20.11.2016	
Auditor:			
Expert:	Mehmed Hasanović	20.11.2016	
Quality Manager Endorsement:			

Distributed to:	Responsible Manager		
	Sector Director		

Sample Check List

Reference	Areas of Audit	Requirement / question	Example of evidence to be reviewed	Status of implementation	Comments[i]
M.B.902 (b) ISO 9001:2008 - 5.5.1	Management responsibility	How is authorisation to verify/sign AWD documents implemented?	- Check signed documents from representative sample of files (5%)	☐ Satisfactory ☐ Not satisfactory Level I Level II Recommendation* ☐ Not applicable	
M.B.102 (c) ISO 9001:2008 - 6.2.2.a)	Management responsibility	Is all staff involved in Airworthiness activities appropriately qualified and do they have appropriate knowledge, experience, initial training and continuation training to perform their allocated tasks? Is State exam the condition for authorization? Which kind of State exam? What staff needs authorization? Auditors, inspectors, experts ...? How can a person be authorized as auditor, inspector, ..etc?	Is a formal procedure established for evaluating staff qualifications? Check 5 % sample of staff records See AMC for : Detailed qualification requirement - Practical experience - Basic knowledge - Audit training - 5 years relevant work experience to be an inspector - Engineering degree - Aircraft type training - Knowledge of maintenance standards With inspector skills and a continuation training programme	☐ Satisfactory ☐ Not satisfactory Level I Level II Recommendation* ☐ Not applicable	
ISO 9001:2008 - 6.2.2. b) e)	Management responsibility	Are training and other necessary action taken? Are appropriate authorized staff records maintained? Do records contain evidence of training and experience?	See records	☐ Satisfactory ☐ Not satisfactory Level I Level II Recommendation* ☐ Not applicable	

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Continuous Monitoring of the Audit Program

- The person managing the audit program should monitor its implementation considering the need to:
  - evaluate conformity with audit programs, schedules and audit objectives;
  - evaluate the performance of the audit team members;
  - evaluate the ability of the audit teams to implement the audit plan;
  - evaluate feedback from top management, auditees, auditors and other interested parties.

Review and improvement of the Audit Program

- The person managing the audit program should review the audit program to assess whether its objectives have been achieved.
- Lessons learned from the audit program review should be used as inputs for the continual improvement process for the program.
- The audit program review should consider the following:
  - results and trends from audit program monitoring;
  - conformity with audit program procedures;
  - audit program records;
  - alternative or new auditing methods;
  - effectiveness of the measures to address the risks associated with the audit program;
  - confidentiality and information security issues relating to the audit program.
- The person managing the audit program should review the overall implementation of the audit program, identify areas of improvement, amend the program if necessary and report the results of the audit program review to the top management.

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End of presentation

Thank you for your attention!

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Quality Documentation and Records

Omer Pita and Salvador Alepuz
Airworthiness Experts

Your safety is our mission.

An Agency of the European Union

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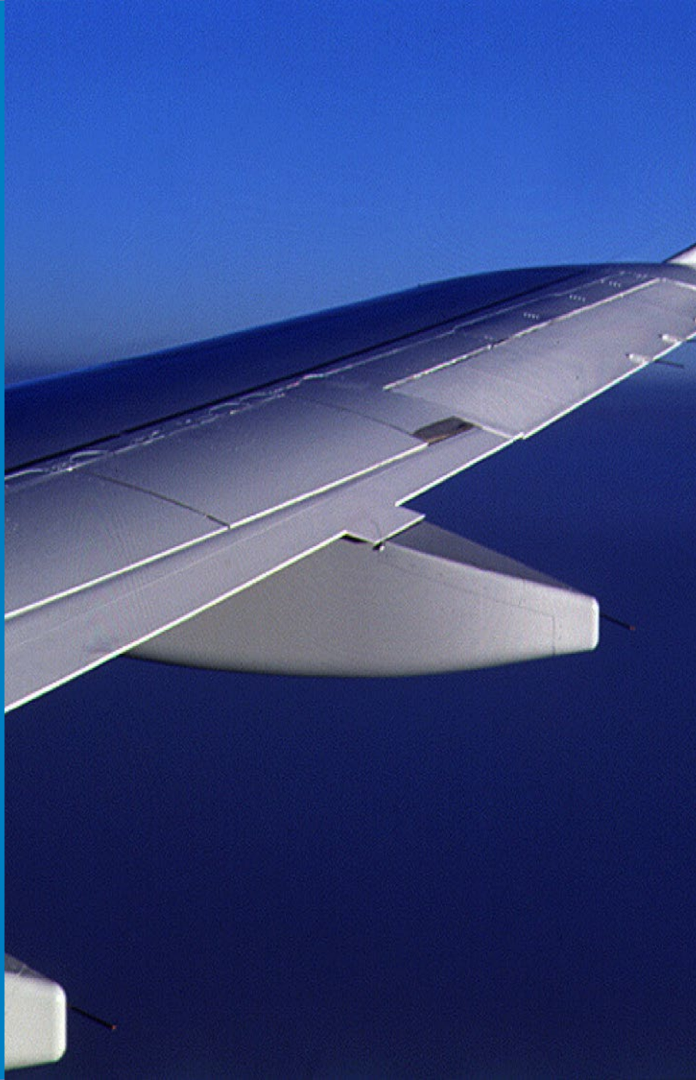
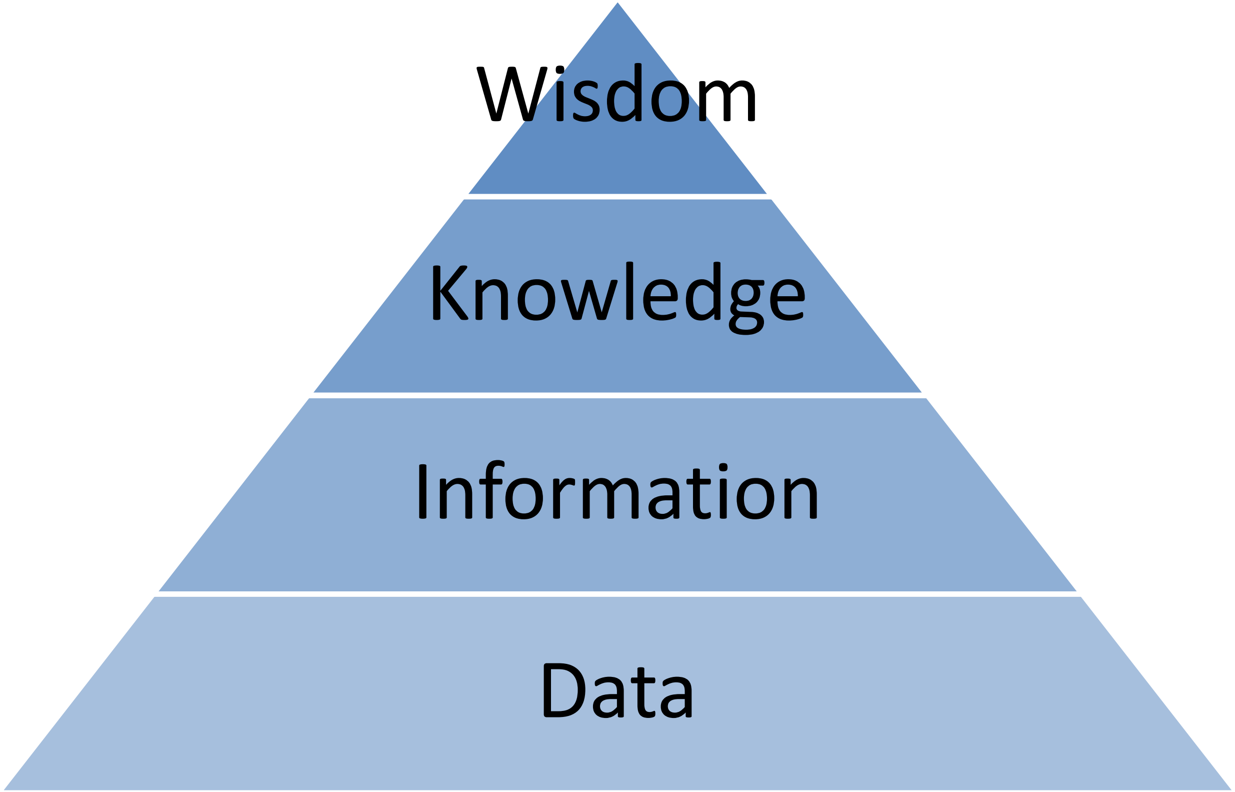
Introduction



Introduction

- Definitions of Information and Knowledge (among many definitions):
  - Information is organized or structured data, which has been processed in such a way that the information now has relevance for a specific purpose or context, and is therefore meaningful, valuable, useful and relevant.
  - Knowledge is a fluid mix of framed experience, values, contextual information, expert insight and grounded intuition that provides an environment and framework for evaluating and incorporating new experiences and information.
    It originates and is applied in the minds of knowers.
    In organizations it often becomes embedded not only in documents and repositories but also in organizational routines, processes, practices and norms.
- All creative human activities are based on Information and Knowledge

DIKW Pyramid



EASA
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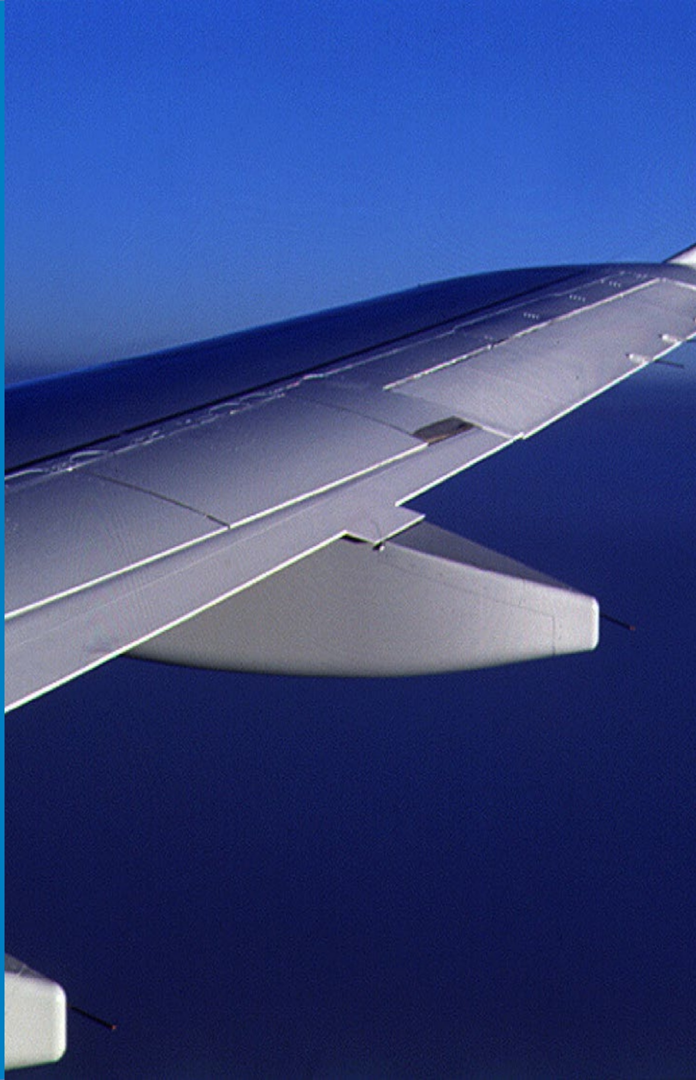
Documentation Structure



ISO9001:2015 Requirement

→ The organization's quality management system shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness

For aviation purposes, this requirement should be read:

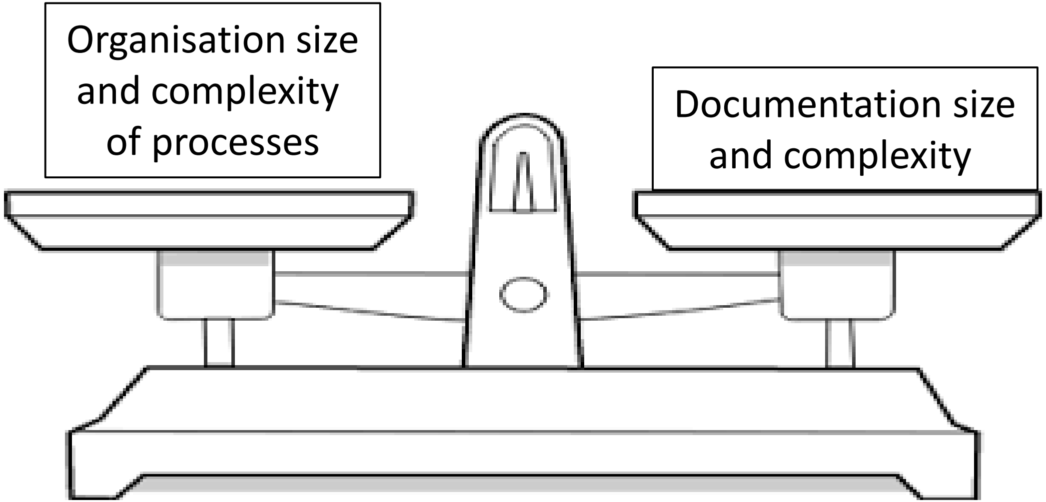
→ The organization's quality management system shall include:

a) documented information required by applicable regulations;

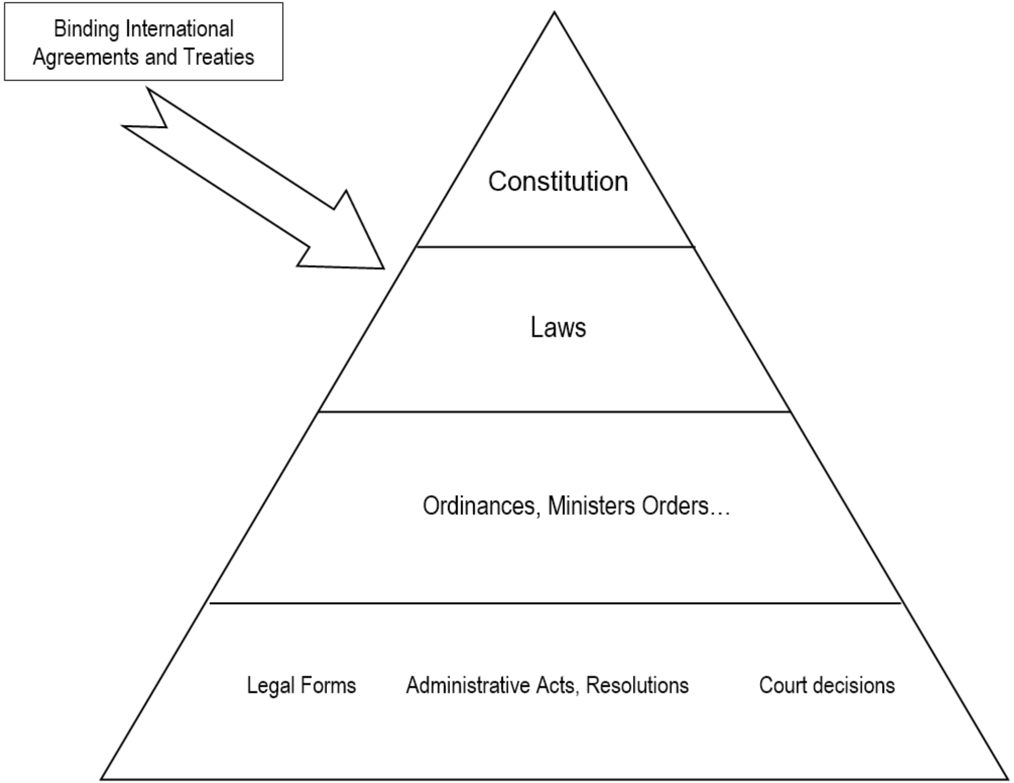
b) documented information determined by the organization as being necessary for the effectiveness

ISO9001:2015 Requirement

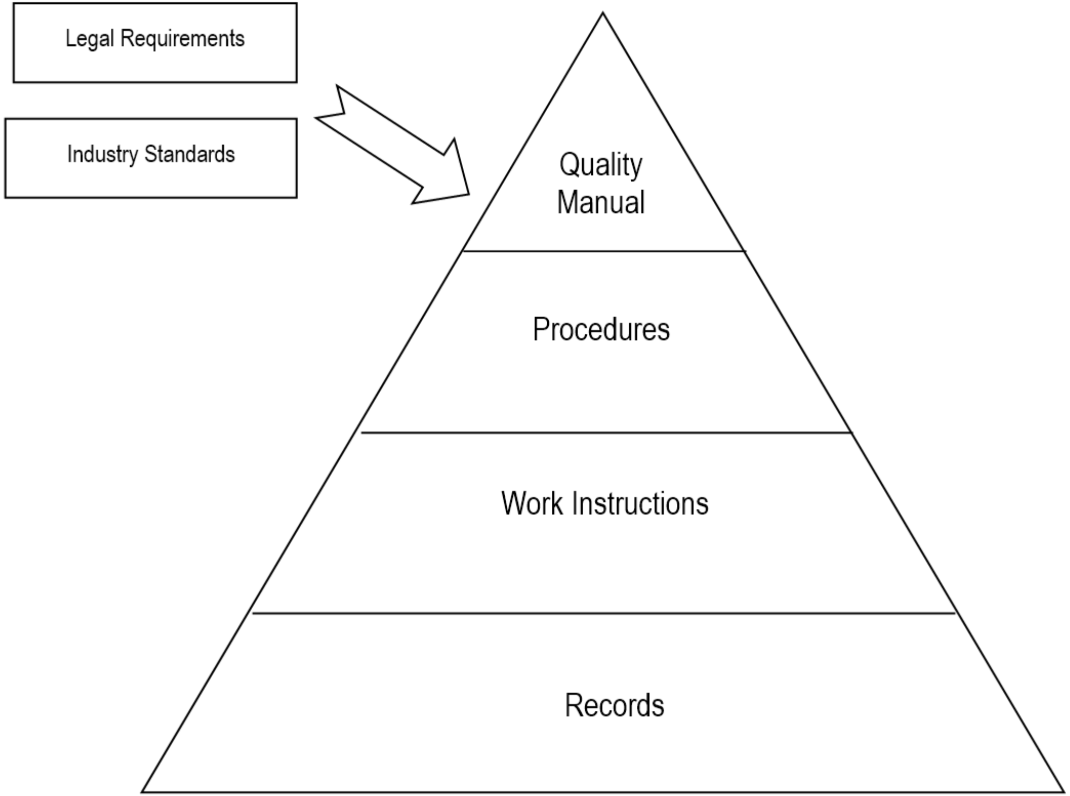
- NOTE (ISO9001:2015): The extent of documented information for a quality management system can differ from one organization to another due to:
  - the size of organization and its type of activities, processes, products and services;
  - the complexity of processes and their interactions;
  - the competence of persons.



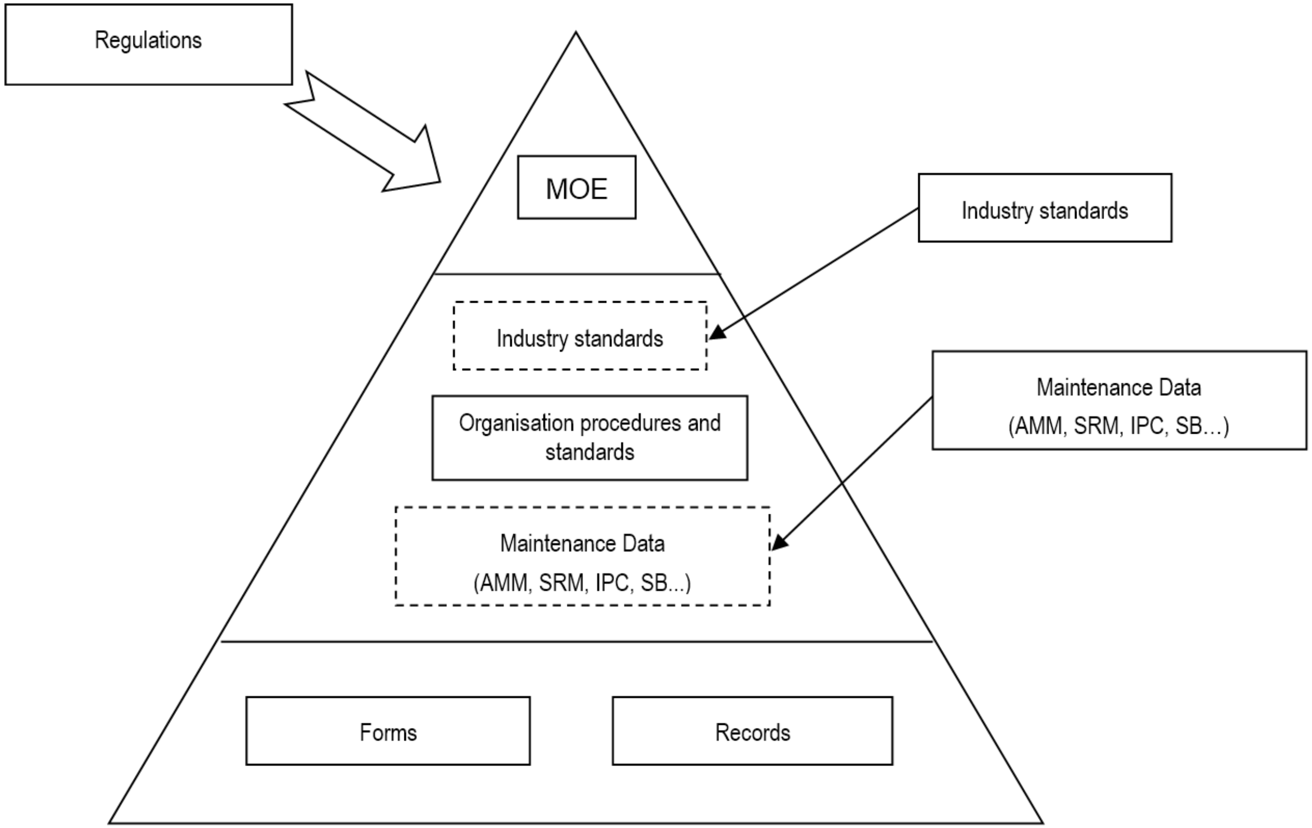
Generic Structure of State Regulations



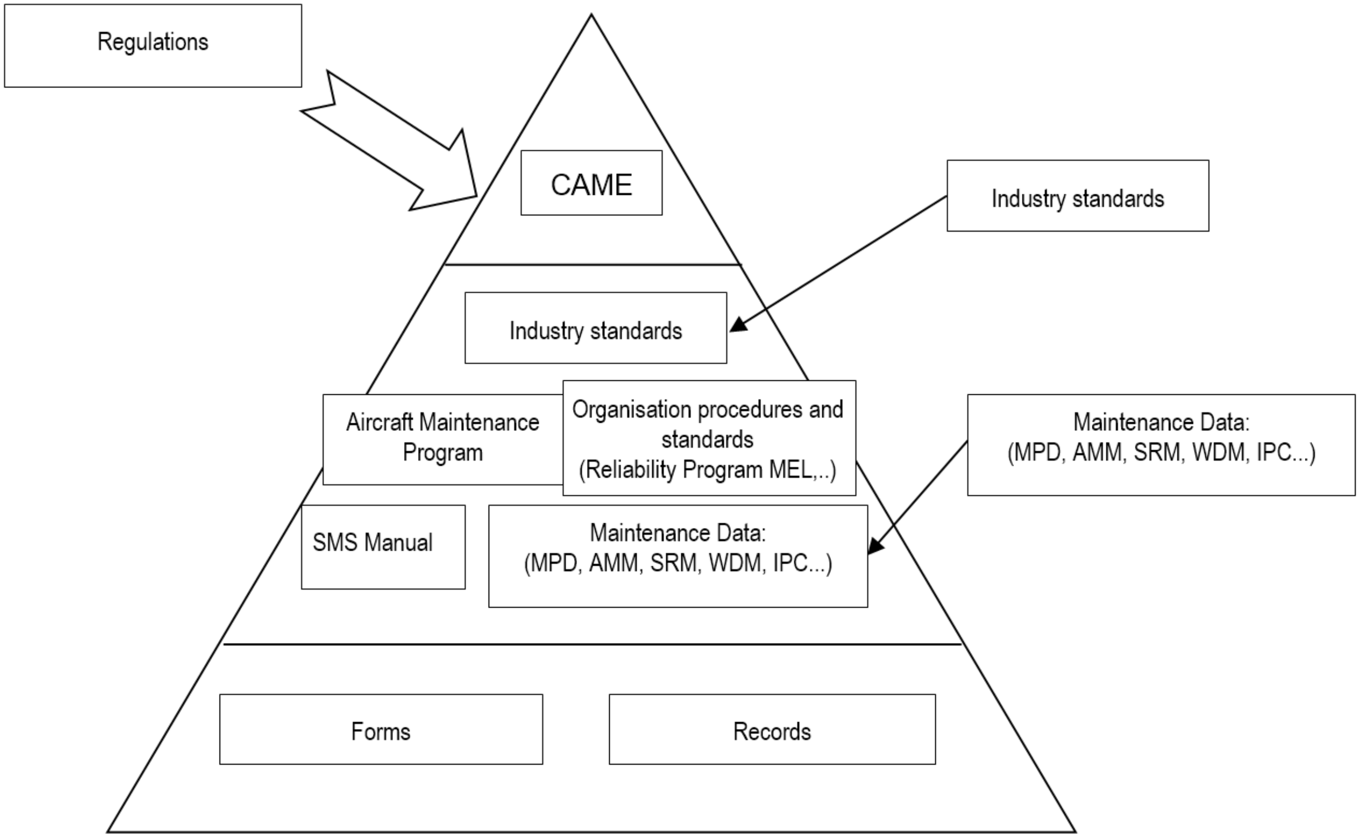
Typical Structure of Quality Documentation



Structure of Documentation for Maintenance Organization



Structure of Documentation for CAMO Organization



Classification of Documentation – Types of Documents

- By source: internal and external
- By media used: hardcopy, microfilm, digital…
- By level of control: controlled and uncontrolled
- By contents: manual, process description (map), procedure, work instruction, form, record

Manual

- Comprehensive and step-by-step guide to a particular topic for both beginners and practitioners that also serves as a reference book.
- A manual details what is given and what is required, explains how to put the presented information into practice, and instructs how to solve problems as they occur.
- This term is commonly used interchangeably with handbook.
- Manual can contain any combination of: policies, standards, system descriptions, process descriptions (maps), procedures and forms
- Examples: Aircraft Maintenance Manual, Airplane Operating Manual, Maintenance Organization Exposition Manual, Quality Manual

Policies

- Policy:
  The set of basic principles and associated guidelines, formulated and enforced by the governing body of an organization, to direct and limit its actions in pursuit of long-term goals.
- Policy Statement:
  Formal document outlining the ways in which an organization intends to conduct its affairs and act in specific circumstances.
- Can be part of manual or standalone document


COREL PHARMA CHEM

QUALITY POLICY

To deliver speciality polymers and its derivatives to meet and exceed customer expectations of Quality, Price, Delivery and Technical support.

This policy shall be deployed through :

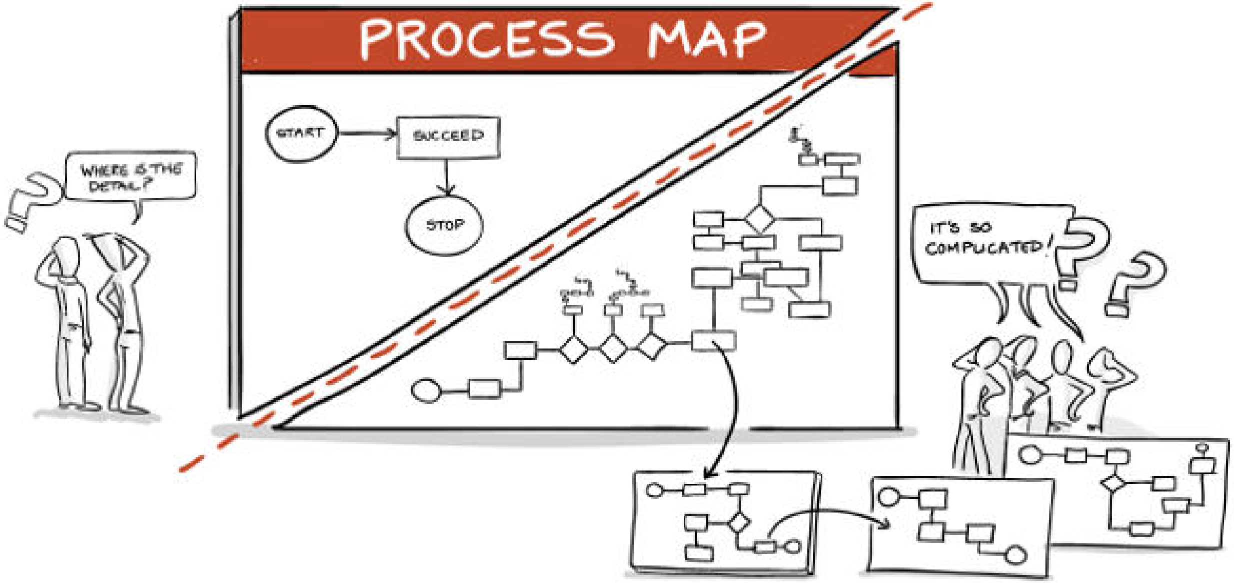
- Continual research & development to discover innovative polymers.
- Continual improvement in product quality by research & development, process control and variability reduction.
- Upgradation of manufacturing technology and skills.
- Cost reduction through elimination of waste in all business processes.
- Development of human resources.
- Development of overall system as per international standards.

Kirit Patel
Managing Director
01/01/2010

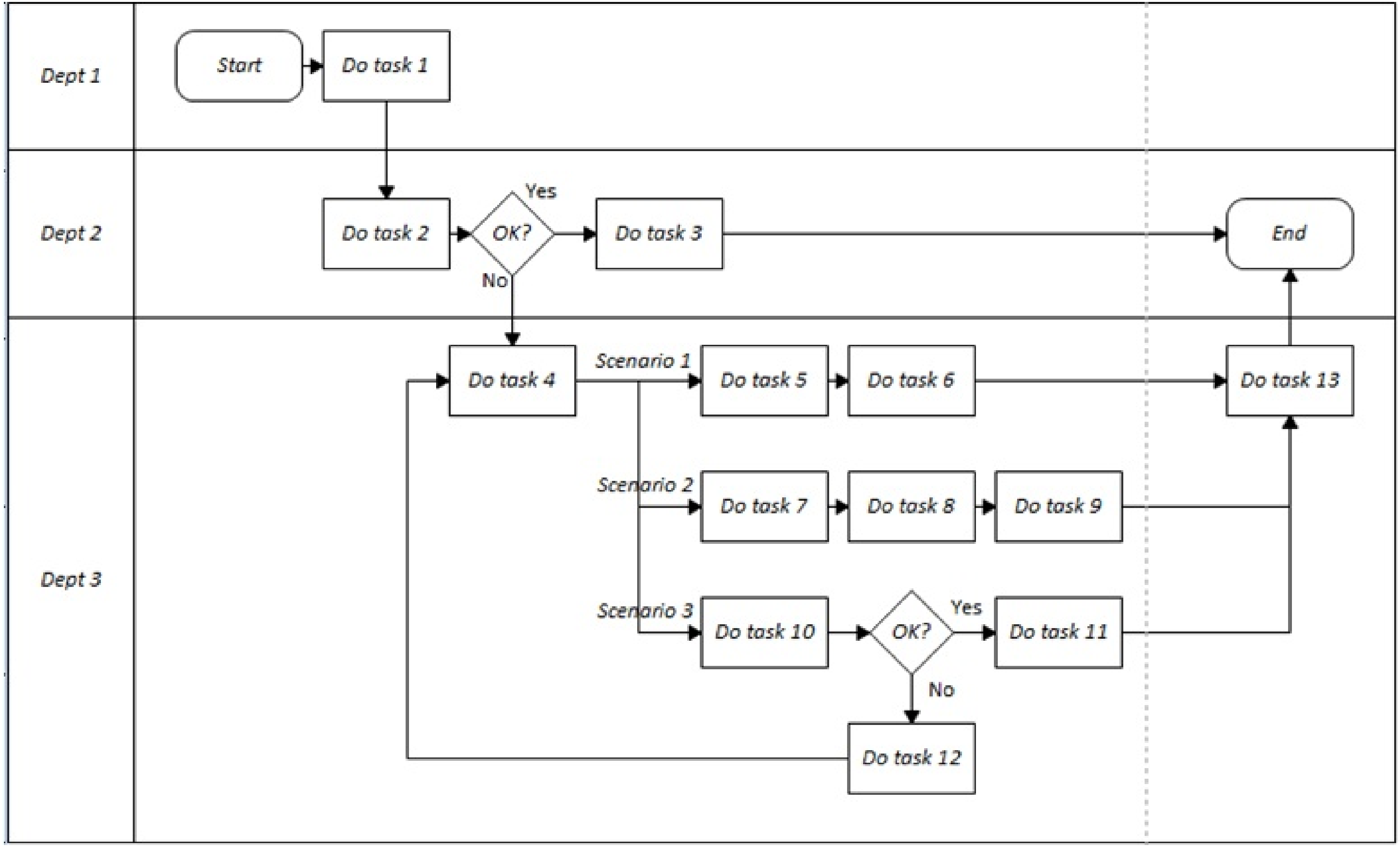
the next generation polymer technologist...

Process

→ Process map or description:
Structural presentation or description of a process flow within an organization.



Process Map Example

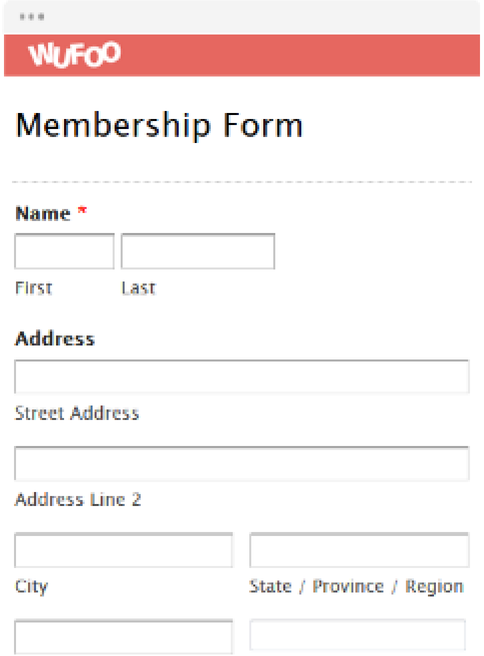


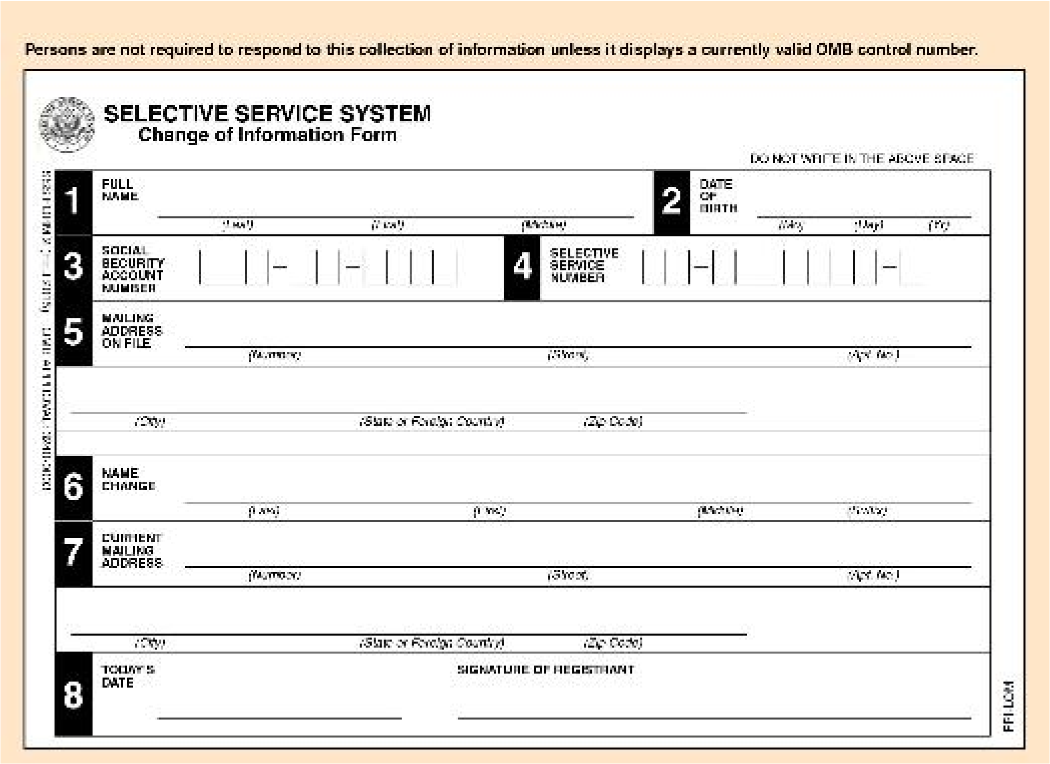
Documented Procedure and Work Instruction

- Procedure:
  Description of step-by-step sequence of activities or course of action that must be followed as described and in the same order to correctly perform a task.
- Difference between Procedure and Work Instruction
  - These two terms are frequently used interchangeably but in general,
  - Procedure (in a sense of quality documentation) would involve more workers of different skills, while
  - Work Instruction can be followed by one worker
  - But, there are different examples like „pilot procedure” in flight ops manuals or „Job Instruction” in AMM

Forms

→ Logically structured document with a fixed arrangement of captioned spaces, designed for entering, extracting, or communicating the required information.




Persons are not required to respond to this collection of information unless it displays a currently valid OMB control number.

SELECTIVE SERVICE SYSTEM
Change of Information Form

1 FULL NAME
2 DATE OF BIRTH
3 SOCIAL SECURITY ACCOUNT NUMBER
4 SELECTIVE SERVICE NUMBER
5 MAILING ADDRESS ON FILE
(City) (State or Foreign Country) (Zip Code)
6 NAME CHANGE
7 CURRENT MAILING ADDRESS
(City) (State or Foreign Country) (Zip Code)
8 TODAY'S DATE
SIGNATURE OF REGISTRANT

Records

- → Records are original documents such as signed off Job Cards, Work Orders, Aircraft Log Books, Component Certificates and other documents that support certain activity and/or serve as proof that certain activity has been done.
- → Term „dirty finger copy” is related to original signed off work orders or job cards

Documentation Control

- Quality documents are defined as all those documents produced internally or obtained externally to provide guidance and instructions on how activities are to be performed.
- Due to many changes (revisions) of aviation quality documents, it is essential that only accurate and current version of quality document is used. Therefore such documents are identified as controlled documents.

Documentation Control

- Any copy made from the controlled document (printed or copied) is considered non-controlled.
- To assure that up-to-date version of an controlled document is always available and used, distribution of such documents is limited to minimal required number of places.
- Documentation control system provides a consistent set of document management rules for the management of controlled quality documentation.

Documentation Control

- Documentation Control system should comprise following:
  - Mandatory contents of controlled documents
  - Design standard of controlled documents (font, page margins, layout of document page…)
  - Publication procedure
  - Revision procedure
  - Withdrawal of document
  - Obsolete documents procedure
  - Control of Records

Mandatory Content of Controlled Document

- Each controlled internal document must contain following elements:
  - Document code
  - Revision mark
  - Name of the owner (organizational unit)
  - List of Distribution
  - List of Revision
  - List of Effective Pages
  - List of Referent Standards (documents)

Distribution List

→ Defines: where (to whom) and in what media document is distributed.

DISTRIBUTION LIST

Copy No.	USER	MEDIA	QTY
1.	Library Department	Original - hard copy Digital	1 1
2.	Company's Intranet web page	Digital	1
3.	CAA	Digital	1

List of Revisions

LIST OF REVISIONS

No.	Date	Inserted by	No.	Date	Inserted by
0	01.05.2009.				
1	05.09.2009.				
2	04.01.2010.				
3	15.05.2010.				
4	01.06.2010.				
5	15.11.2010.				
6	14.01.2011				
7	10.10.2011.				
8	01.07.2012				
9	15.03.2013				
10	01.08.2013				

EASA

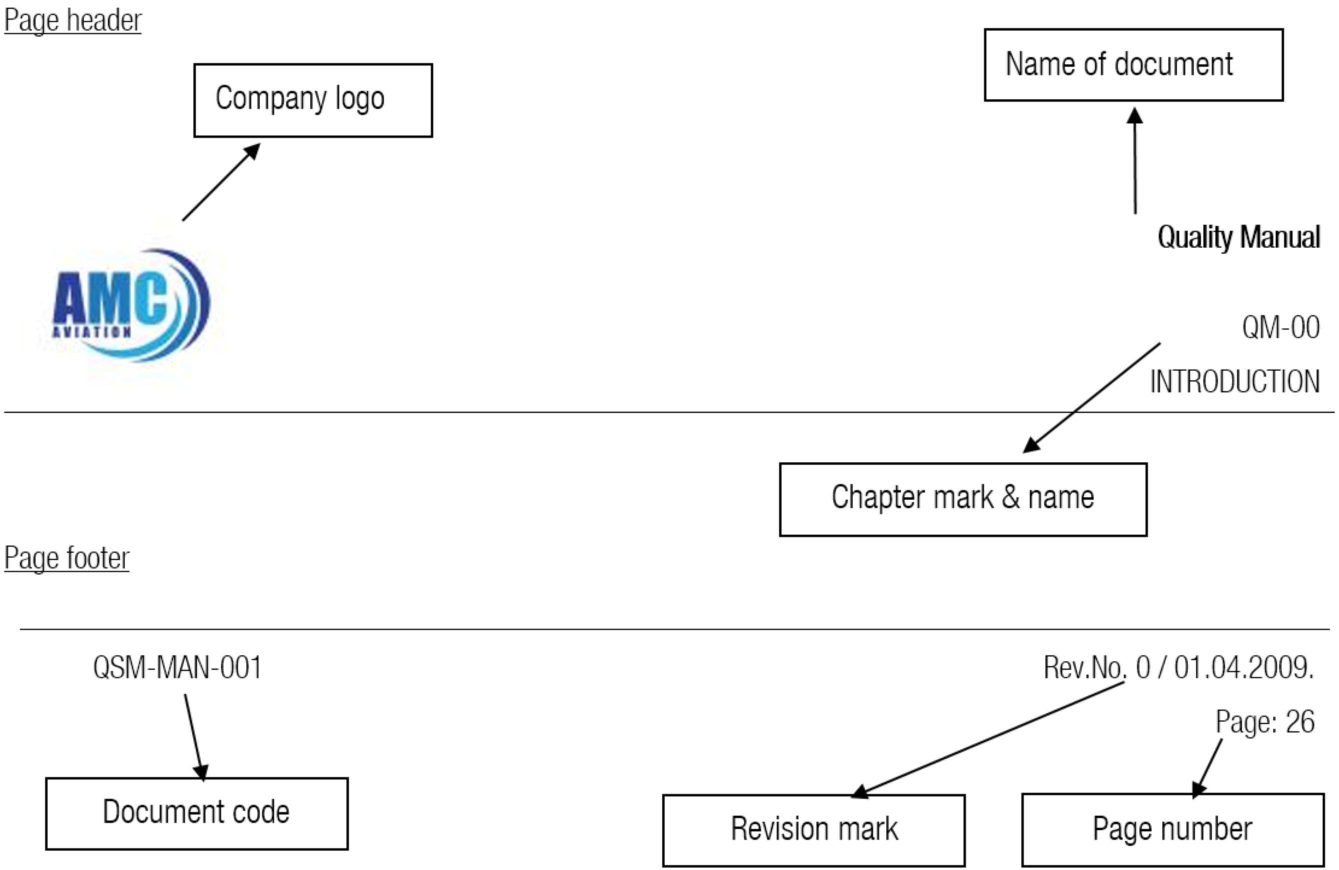
List of Effective Pages

→ Enables verification that the document is complete and current

LIST OF EFFECTIVE PAGES

Chapter	Page	Rev.	Date	Chapter	Page	Rev.	Date
00	2	9	15.03.2013	70	44	9	15.03.2013
00	3	9	15.03.2013	70	45	9	15.03.2013
00	4	9	15.03.2013	70	46	9	15.03.2013
00	5	9	15.03.2013	70	47	9	15.03.2013
00	6	9	15.03.2013	70	48	9	15.03.2013
00	7	9	15.03.2013	70	49	9	15.03.2013
00	8	9	15.03.2013	70	50	9	15.03.2013
00	9	9	15.03.2013	70	51	9	15.03.2013
00	10	9	15.03.2013	70	52	9	15.03.2013
00	11	9	15.03.2013	70	53	9	15.03.2013
00	12	9	15.03.2013	70	54	9	15.03.2013
10	13	9	15.03.2013	80	55	9	15.03.2013
10	14	9	15.03.2013	80	56	9	15.03.2013
10	15	9	15.03.2013	80	57	9	15.03.2013
10	16	9	15.03.2013	80	58	9	15.03.2013
20	17	9	15.03.2013	80	59	9	15.03.2013
20	18	9	15.03.2013	80	60	9	15.03.2013
30	19	9	15.03.2013	80	61	9	15.03.2013
40	20	9	15.03.2013	80	62	9	15.03.2013
40	21	9	15.03.2013	80	63	9	15.03.2013
40	22	9	15.03.2013	80	64	9	15.03.2013
40	23	9	15.03.2013	APP	65	9	15.03.2013
40	24	9	15.03.2013		66	9	15.03.2013
40	25	9	15.03.2013		67	9	15.03.2013
40	26	9	15.03.2013		68	9	15.03.2013
40	27	9	15.03.2013		69	9	15.03.2013
40	28	9	15.03.2013		70	9	15.03.2013

Example of Controlled Document Page Markings



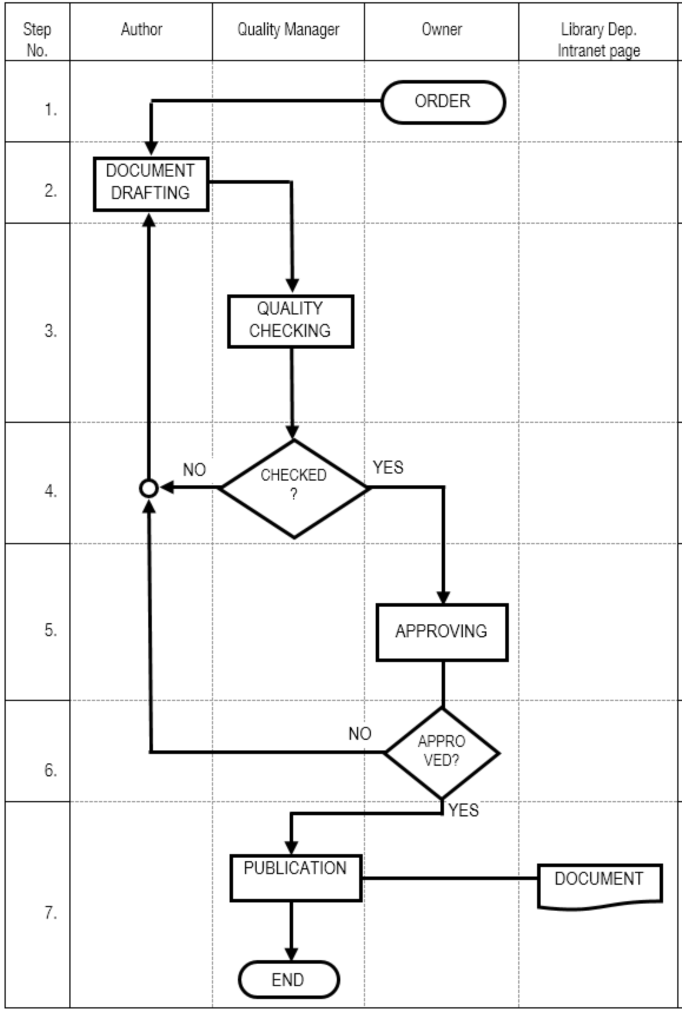
Document Approval

→ At the bottom of the each page of List of Effective Pages, there shall be an approval table with data and signatures of the person(s) who prepared the document (Author(s)), the person who controls the document (Quality Manager) and the person(s) who approves the document (Owner). The table can be in following form:

	Name and position	Date	Signature
Prepared by:			
Quality Check by:			
Approved by:			

Publication Procedure

- Documents Control process must contain publication procedure like example on the right:



EASA

Obsolete Documents

- Obsolete Documents
  - Use of obsolete documents is not allowed except for training purposes. Such copies must be marked with a sign “TRAINING COPY”.
  - Obsolete document has to be destroyed unless it is going to be used for training purposes.

Control of Records

- Control of records
  - Records provide evidences of conformance with requirements of applicable standards, rules and regulations.
  - Control of records procedure specifies records to be kept, location, organization unit responsible for keeping records, retention period and, if any, specific conditions of keeping/maintaining records.

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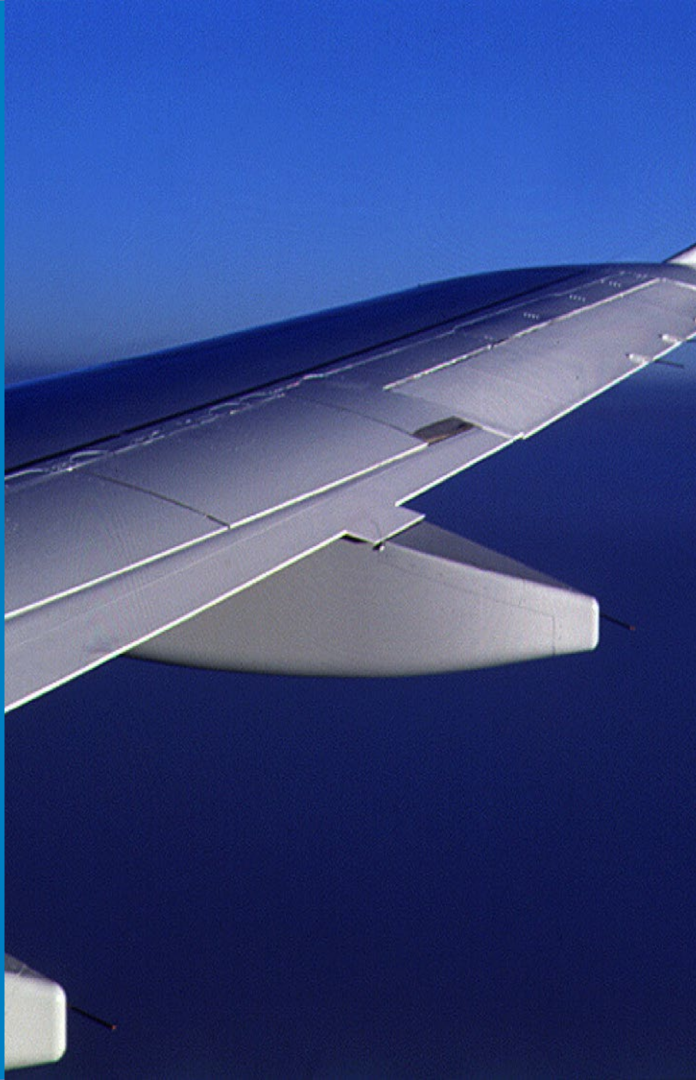
Developing a procedure



When Do We Need Documented Procedure

- We need a documented procedure when activity or task:
  - Is complex
  - Is routine, but it's essential that everyone strictly follows rules
  - Demands consistency
  - Involves mandatory production of records
  - Has serious consequences if done wrong
  - Is required by the regulation

Contents of Procedure

- A procedure should provide answer to following questions:
  - WHY – The purpose of the procedure
  - WHAT – What is done and the methods used
  - WHO – Who carries out the activity, who has responsibility for the activity
  - WHEN – If any specific time constraints are imposed these should be document
  - WHERE – Location of the activity if it is critical to the activity
  - WITH WHAT– could be forms, other procedures, Standards, tools, equipment, software…

Procedure Structure

- Procedure name and/or identification code
- Description of the context
  - Purpose of procedure
  - Position of the procedure within larger process
  - Notes and warnings, safety information
  - References to applicable standards and other procedures
- Preparation information (as applicable)
  - Material, tooling, equipment
  - Facility & environmental requirements
  - Preconditions, job set-up
- Steps
- Closing of procedure
  - Documenting – recording, distribution of records
  - Communicating…

Types of Procedures

- Organizational or system procedures
  - Define organizational activities within the management system
  - Example: Quality documentation publication procedure
- Operating procedures
  - Define product/service realization tasks
  - Example: Engine removal/installation procedure

Methods of Presentation

- In documented procedures we can use following presentation methods:
  - Text
  - Flow Charts
  - Schematic Diagrams
  - Illustrations
  - Tables and Matrices

Textual Procedures

- Almost every procedure must contain textual part.
- Textual part is very useful to describe step by step simple one way flow tasks, context of procedure, function of certain device or system or to emphasize critical parts of procedure.

Textual Procedures

- However, when dealing with complex procedures, strictly textual procedures tend to be:
  - Difficult for understanding complex links and loops between activities,
  - Inefficient and hardly readable as complex matters require many words to accurately describe the system
- Therefore, it is beneficial to use flowcharts and other illustrations in order to simplify the textual part and the whole procedure
- Picture speaks thousand words!

Example of Textual Procedure

MANUFACTURER'S MASTHEAD

MANUAL TITLE

AUGMENTOR VANE ACTUATOR - MAINTENANCE PRACTICES

1. Removal/Installation Augmentor Vane Actuator

   A. Augmentor Vane Actuator - Removal.

      (1) Remove both augmentor tube access panels.

      (2) Disconnect actuator and vane position transmitter electrical plugs.

      CAUTION: OBSERVE SPACER AND WASHER ASSEMBLY SEQUENCE FOR LATER INSTALLATION.

      (3) Remove stabilizer rod attaching bolt at the swinging arm eye bolt.

      (4) Remove eye bolt that attaches the actuator to the swinging arm.

   B. Preparation for Installation.

      CAUTION: ACTUATOR TRAVEL HAS BEEN PRE-SET IN THE SHOP. ADJUSTMENT OF JACKSHAFT OR LIMIT SWITCHES IS NOT PERMITTED: HANDLE ACTUATOR WITH CARE SO AS NOT TO ROTATE ACTUATOR HEAD AND LOSE SHOP ADJUSTMENT.

      (1) Remove augmentor vane transmitter and bracket assembly from the old vane actuator and install transmitter and bracket assembly on the replacement unit in approximately the same position.

         NOTE: There is a right hand and left hand actuator having different part numbers.

      (2) Set vane position transmitter as follows:

         WARNING: EXERCISE EXTREME CAUTION WHEN WORKING WITH ENERGIZED EQUIPMENT.

         (a) Connect actuator electrical plug and ground actuator against the wing structure. Operate augmentor vane control switch in the cockpit to TRAIL. This checks that the actuator is retracted to the trail limit position.

            NOTE: De-icing heat switch must be IN or the auxiliary heat control switch must be at ARM.

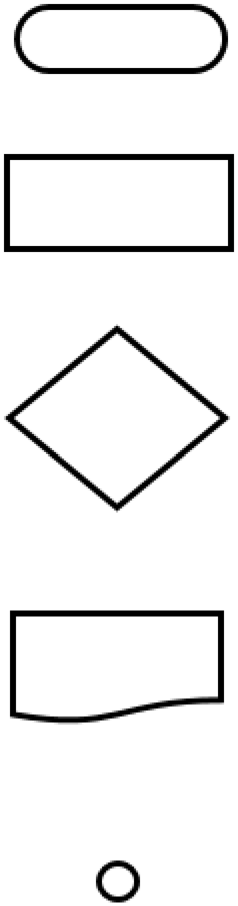
         (b) Connect position transmitter electrical plug. With inverter power ON and actuator grounded, move position transmitter arm clamp on actuator jackshaft so that the indicator pointer in the cockpit is at TRAIL. Secure transmitter assembly.

      (3) Check that actuator limit switch cover has a drain hole properly drilled and located.

EFFECTIVITY: ALL

78-11-02
Page 201
Jun 27/80

Basic Flowchart Symbols



Start / End of process / procedure.

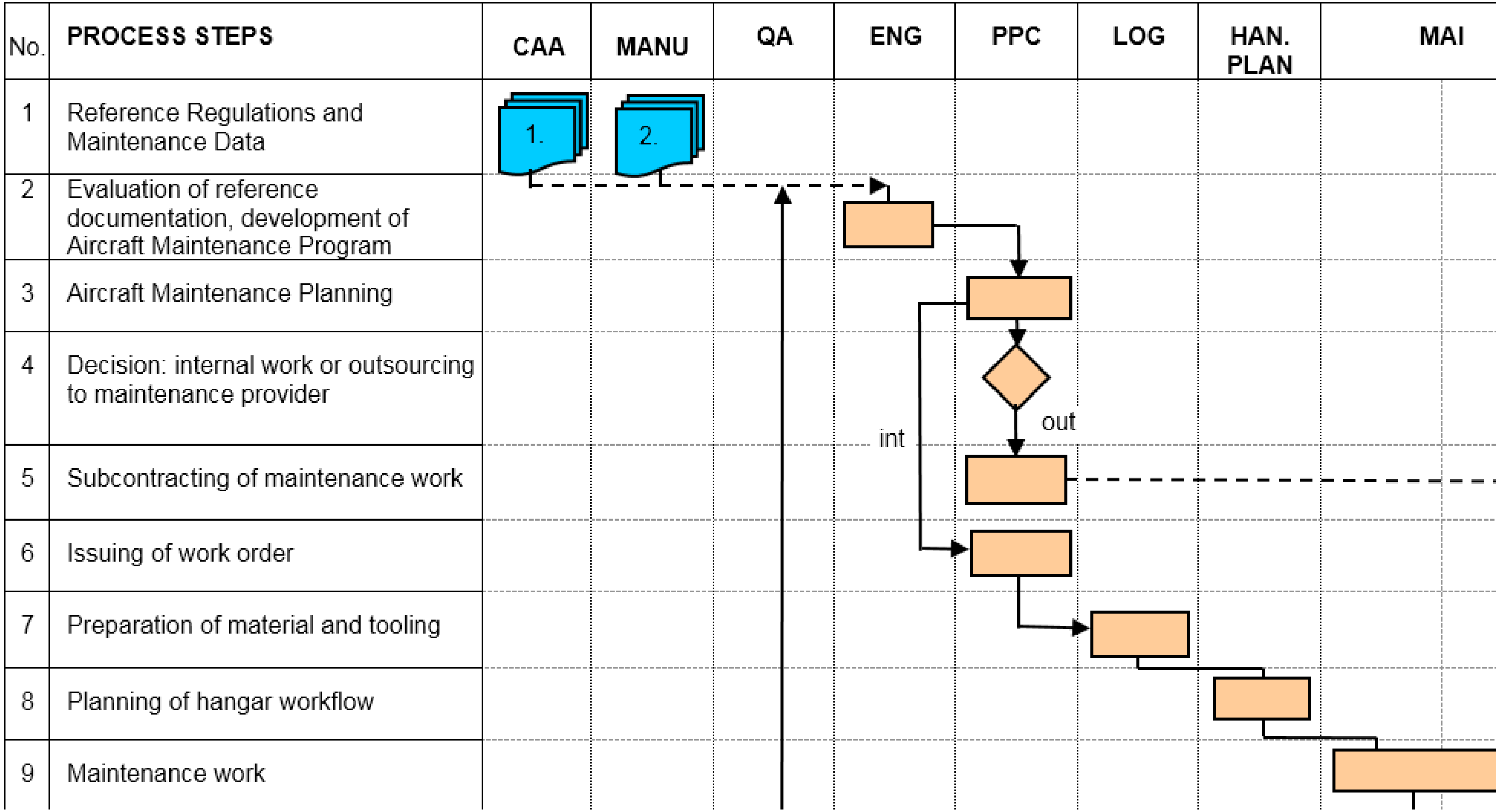
Activity

Check point, checking activity

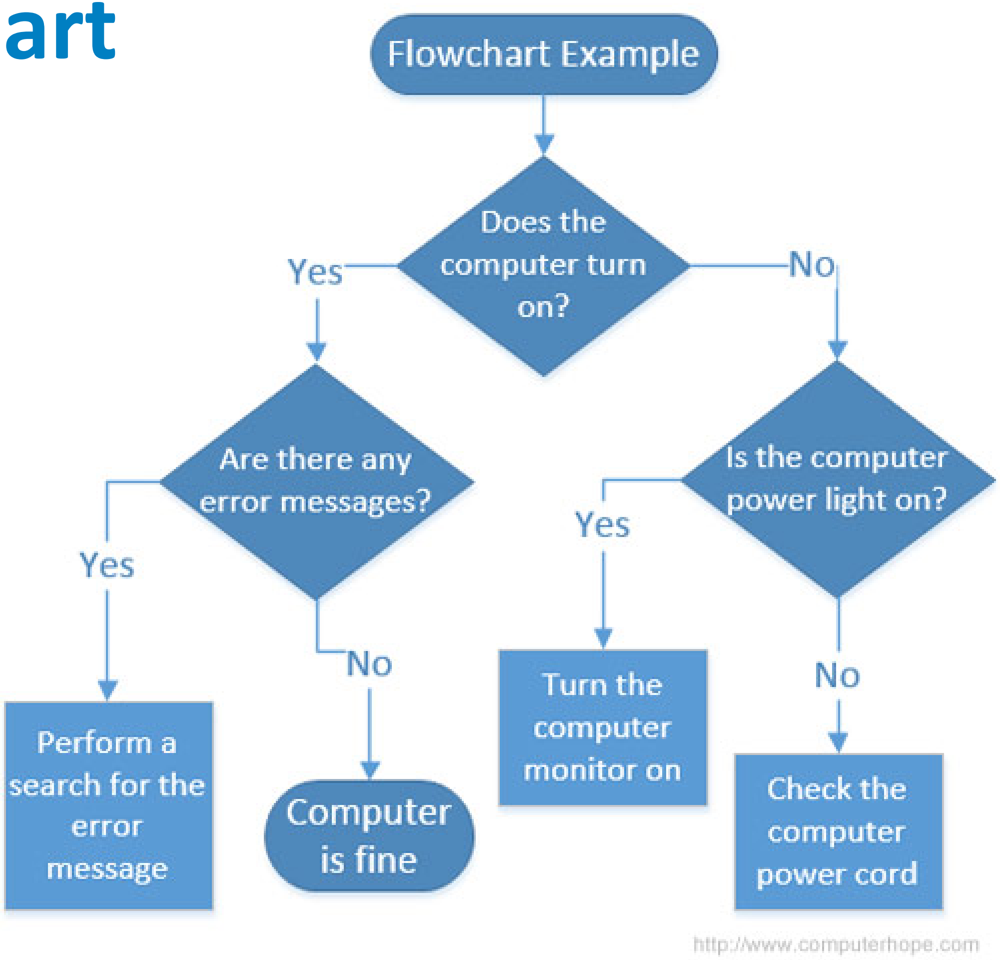
Document, Information

Connection point

Flowcharts: Deming Process Deployment Chart



Standard Flowchart



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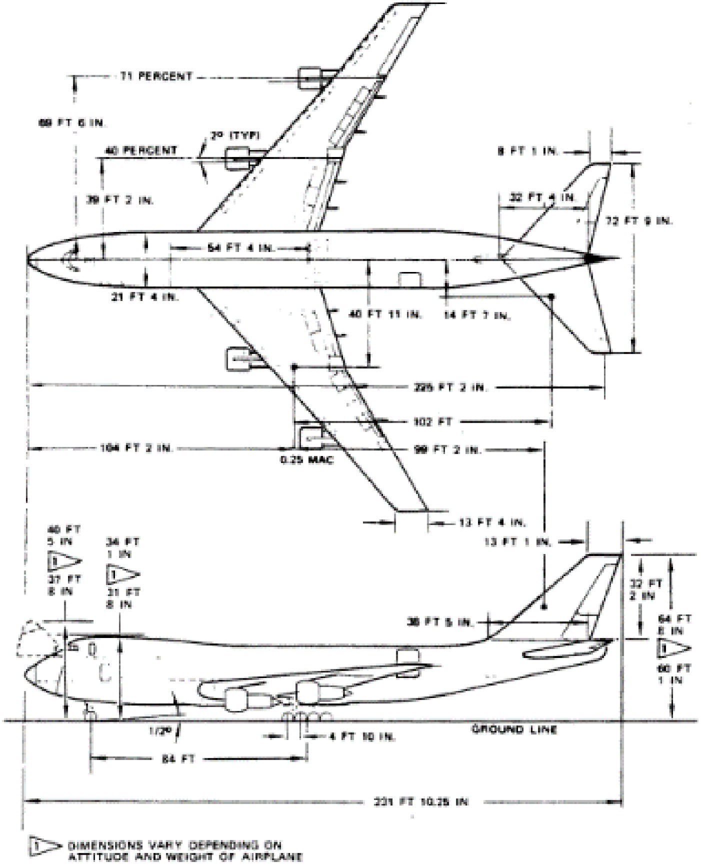
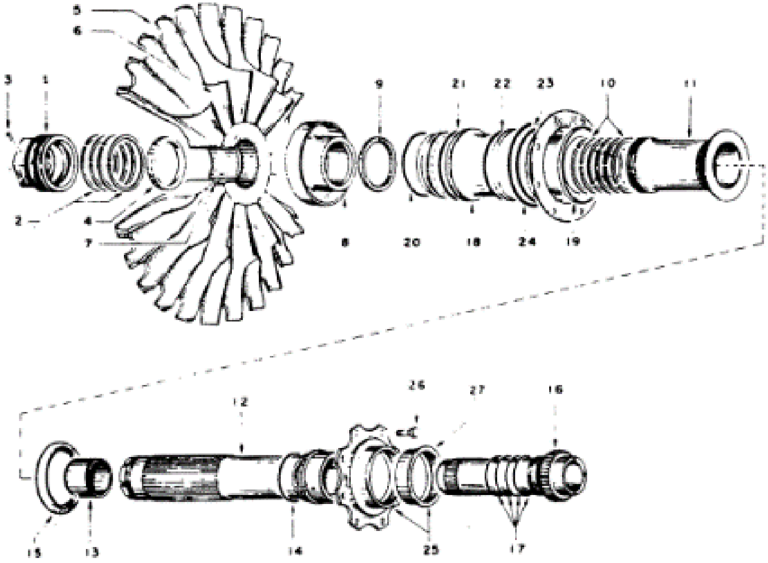
Illustrations

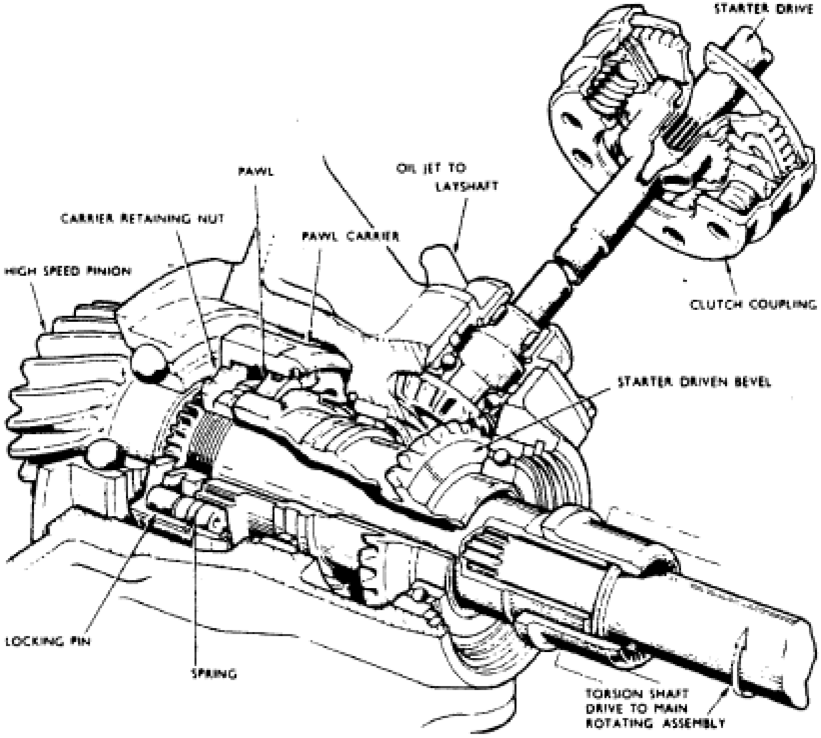




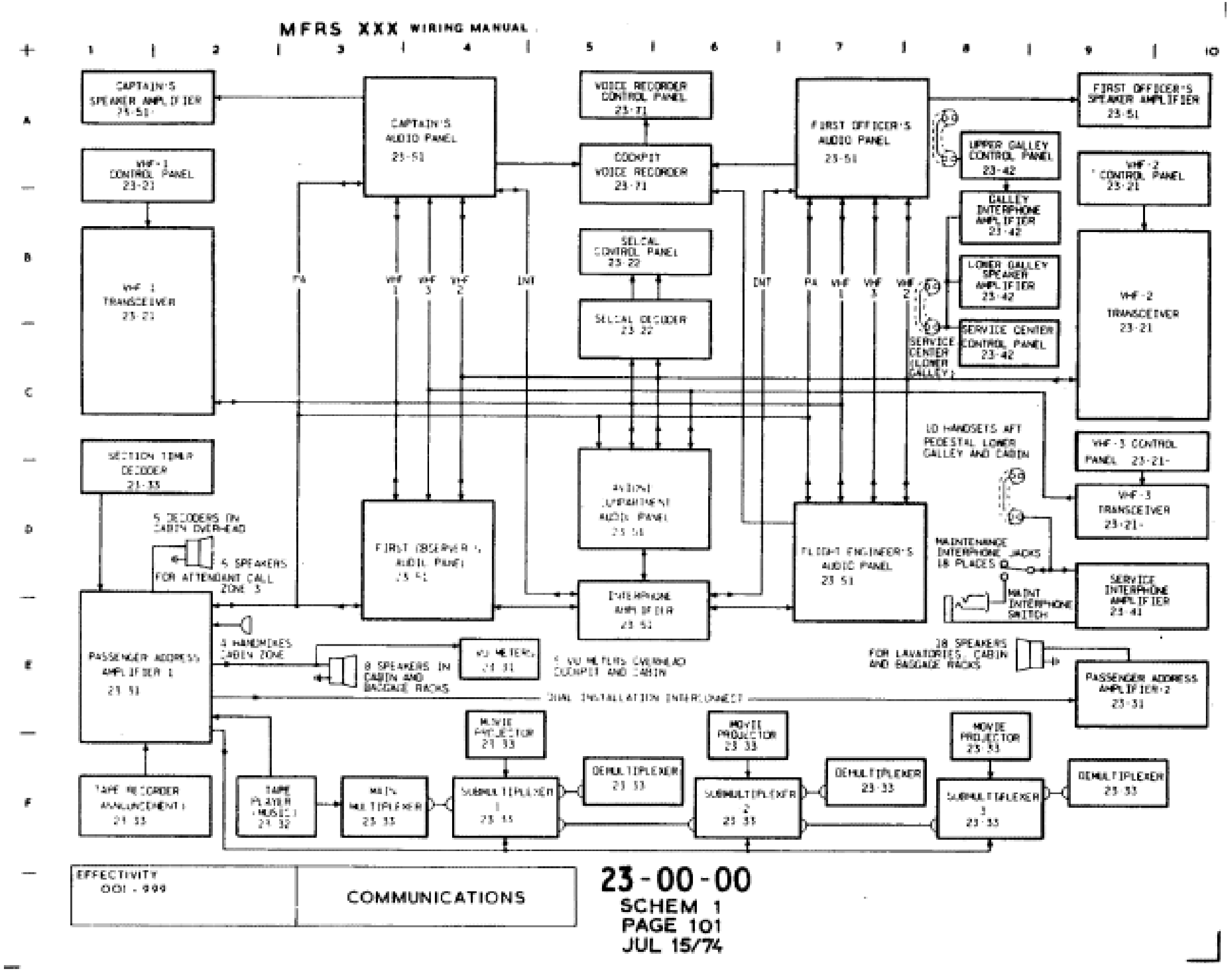
1. Thrust Nut
2. Oil Rings
5. Impeller
6. Inducer
8. Impeller Injection Spinner Spacer
9. Rear Spacer
10. Metal Oil Rings
11. Impeller Shaft Oil Sleeve
12. Impeller Outer Shaft
13. Impeller Outer Shaft Bushing
14. Seal
15. Impeller Shaft Rear Oil Seal
16. Inner Impeller Shaft
18. Rear Housing Outer Sleeve
19. Rear Sleeve Spacer
25. Support and Bushing
27. Impeller Outer Shaft Rear Bushing

EASA

Illustrations



Schematic Diagrams



Tables and Matrices

Matrix of Responsibility

Following Matrix defines responsibilities in the Document Publication procedure.

ACTIVITY \ RESPONSIBILITY	Author	Owner	Quality Manager	Library depart. IT department
Draft preparation (editing)	X			
Quality check			X	
Check of compliance with referent standards, rules & regulations		X		
Approval of document		X		
Publication order			X	
Publication				X
Notification of responsible managers			X	
Notification of affected employees		X		

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Exercise

→ Develop procedure for MEL approval!

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End of presentation

Thank you for your attention!

easa.europa.eu/connect

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An Agency of the European Union

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Quality Systems

Omer Pita and Salvador Alepuz
Airworthiness Experts

Your safety is our mission.

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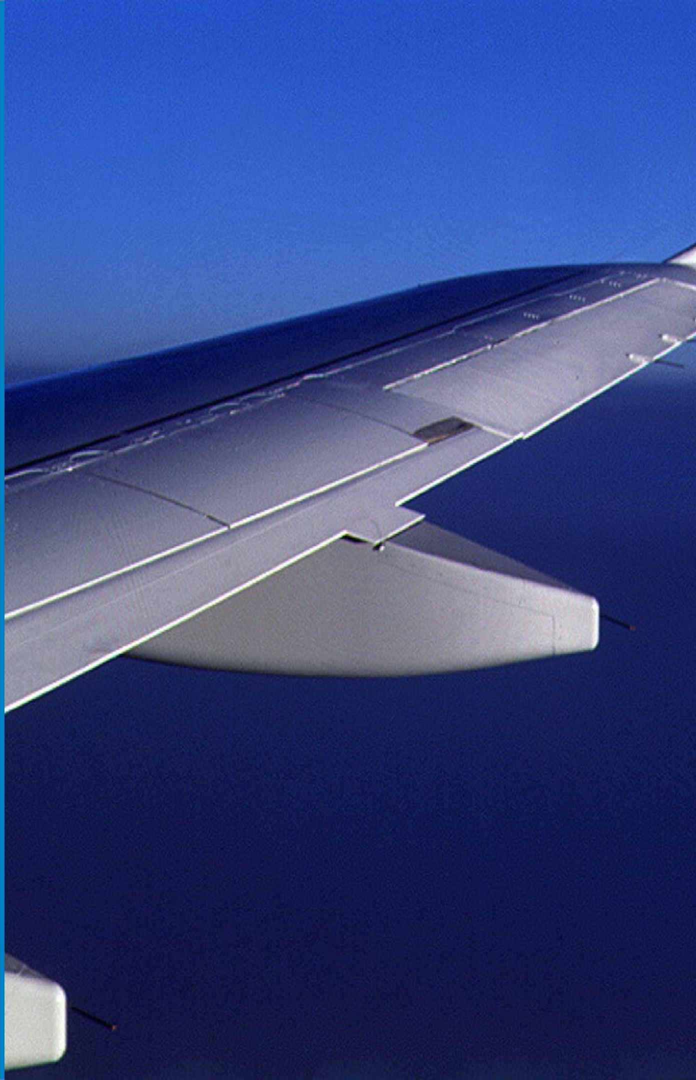
Introduction



Course Contents

- → Quality Management Systems
- → Quality Documentation and records
- → Quality Assurance/Compliance Monitoring Program

Course Contents

- Auditor skills
- Performance of Quality Audit
- Audit Report
- Noncompliance Management
- Corrective Action Procedure
  - Root Cause Analysis
  - Corrective Action Definition
  - Follow up and Closure of Finding

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Quality Management Systems

Context

International civil aviation is a very complex system

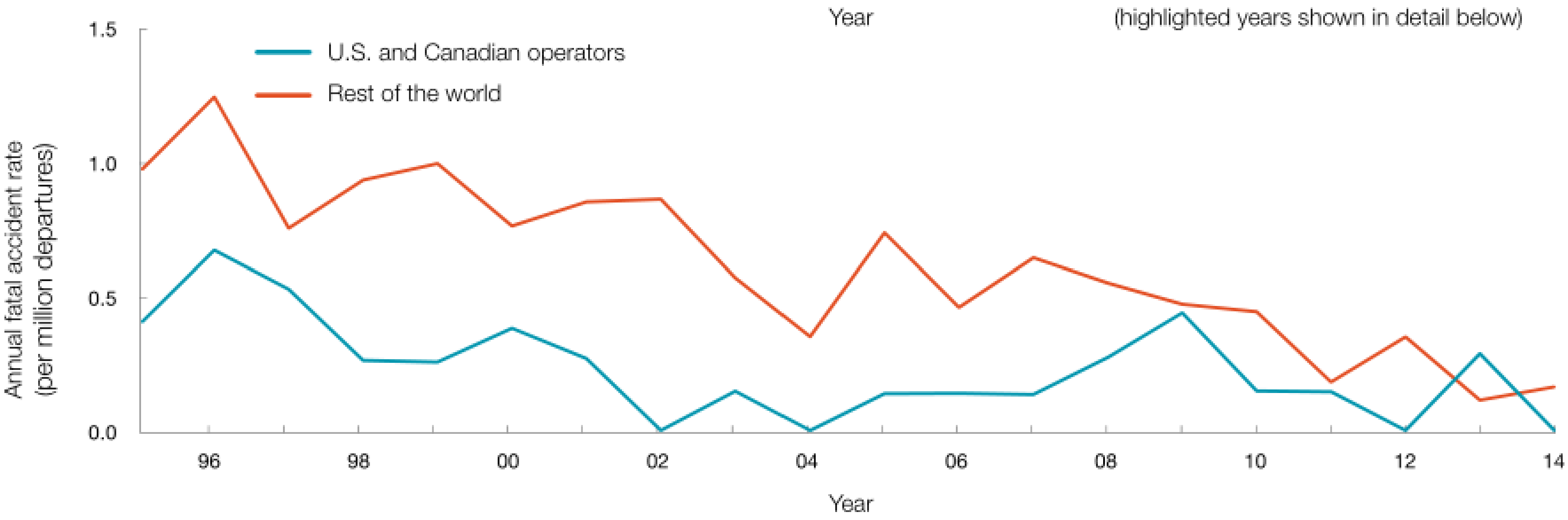
Since the beginning of commercial aviation there has been a steady growth of the volume of operations

Source: Jet Information Services, Inc.

* Certified jet airplanes greater than 60,000 pounds maximum gross weight, including those in temporary non-flying status and those in use by non-airline operators. Excluded are commercial airplanes operated in military service and CIS/USSR-manufactured airplanes.

EASA

At the same time, aviation safety is continuously improving



EASA

How was that possible?

- There are several contributors to achieved safety improvements. Here are some of the more prominent contributions:
  - Technology improvements
  - Application of advanced design (e.g.. damage tolerant and fail safe design)
  - Improved safety regulations
  - Improvement in safety culture
  - Application of HF and CRM principles

    and
  - Implementation of effective Quality Management Systems in the aviation organizations

Humans are Prone to do errors

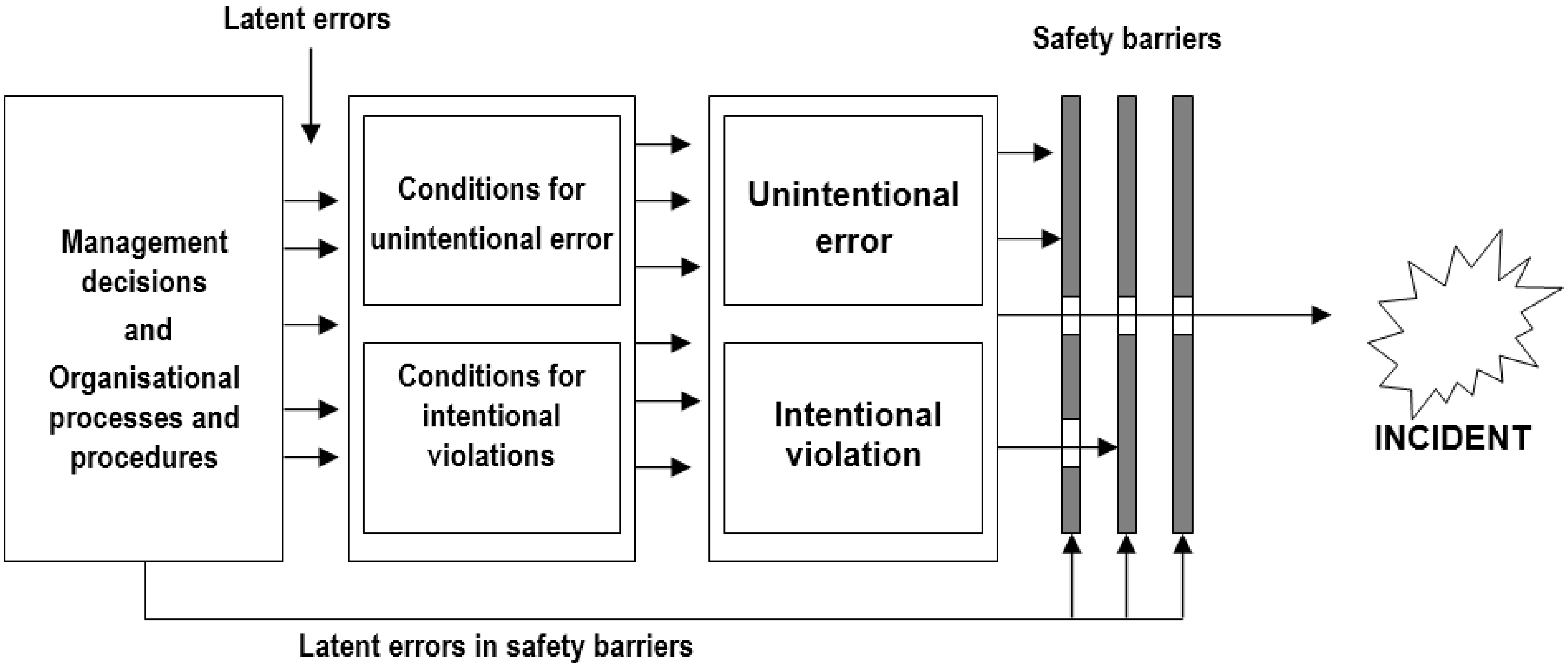
Aviation Statistics – United States

Some of the facts, figures, and examples directly or indirectly concerned with the occurence of **human error in aviation maintenance** are as follows:

- A study revealed that approximately **18% of all aircraft accidents are maintenance related** [6,7];
- As per Ref. [8] maintenance error contributes to 15% of air carrier accidents and **costs** the United States industry over **$1 billion dollars annually**;
- According to a Boeing study **19.1% of in-flight engine shutdowns are caused by maintenance** error [8];
- A study reported that maintenance and inspection are the factor in approximately **12% of major aircraft accidents** [9,10];
- A study of 122 maintenance errors occurring in a major airline over a period of three years revealed that their breakdowns were:
  - **omission (56%)**
  - **wrong installations (30%)**
  - **incorrect parts (8%)**
  - **and other (6%)** [11, 12]

Source:
Human Reliability, Error, and Human Factors in Engineering Maintenance with Reference to Aviation and Power Generation
B . S . Dhillon
CRC Press 2009 Pages 99–112
Print ISBN: 978-1-4398-0383-7
eBook ISBN: 978-1-4398-0384-4
DOI: 10.1201/9781439803844.ch8

James Reason’s Organizational Concept of Human Error



Development of organisational error – source James Reason

EASA

Quality Management Systems

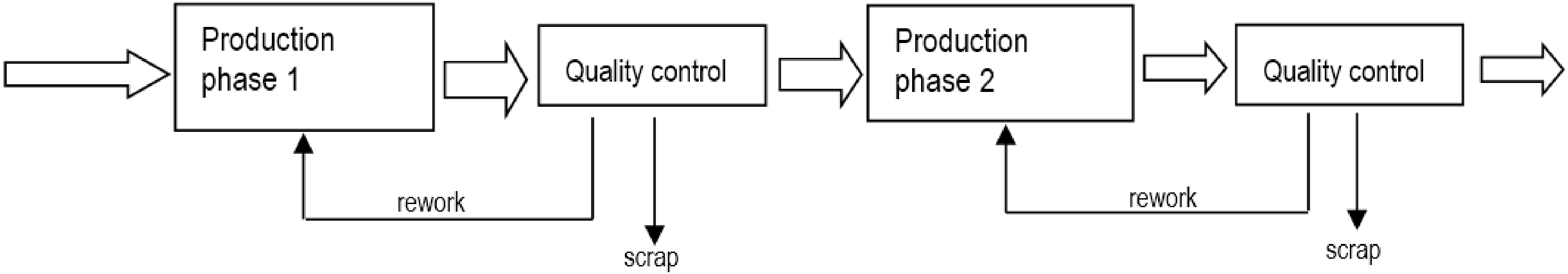
Quality Basics

Definition of Quality

- Term quality is conceptual, perceptual and subjective. Consequently, there is a wide variety of perceptions of quality.
- Here are some of definitions of quality:
  - Quality – degree to which a set of inherent characteristics fulfills requirements (ISO definition)
  - Quality is the ability of a product/service to meet the required characteristics set by the user.
  - Quality is non-inferiority or superiority of something;
  - Quality is fitness for purpose
  - Quality is conformance to requirements
- When we look at the EASA regulatory requirements regarding quality systems, it is indicative that recently published regulations consistently use term „compliance monitoring" which would imply that the term quality (as used in aviation regulations) means <u>compliance with the applicable requirements</u>.

History of Quality Management Development

→ Quality Control Phase:



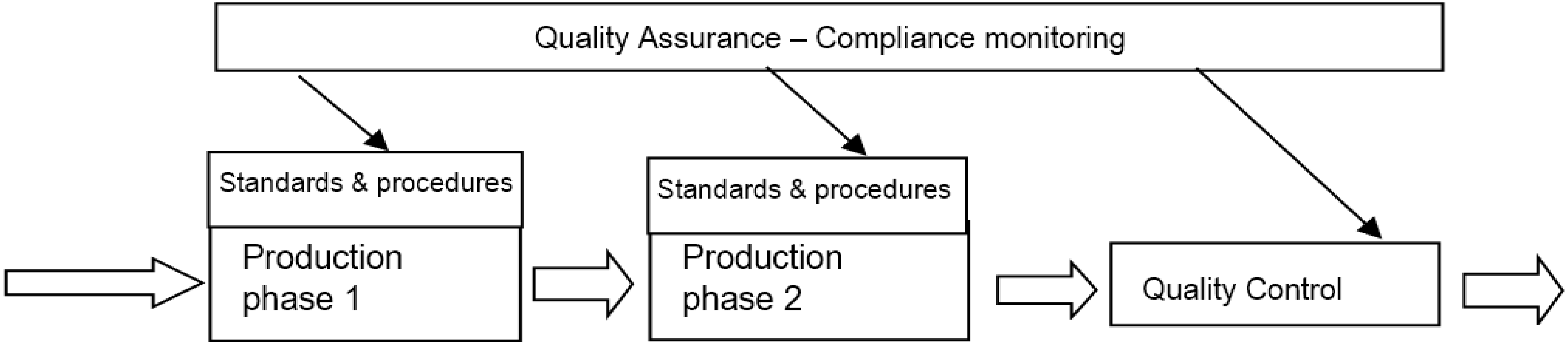
→ No prevention of faulty production, but adequate quality assured for end user through elimination of faulty products

→ Quality with <u>high costs</u> of scraped and reworked products

→ Applies only to production, <u>can not be efficiently applied to services e.g. Flight operations</u>

History of Quality Management Development (cont'd)

→ Quality Assurance Phase:



- Quality assurance component acts preventive through compliance monitoring of implemented prescribed procedures and standards of production
- Frequency of quality control points decreased due to „assured" quality
- Cost effective due to decreased production of faulty products
- Quality assurance is applicable also for services

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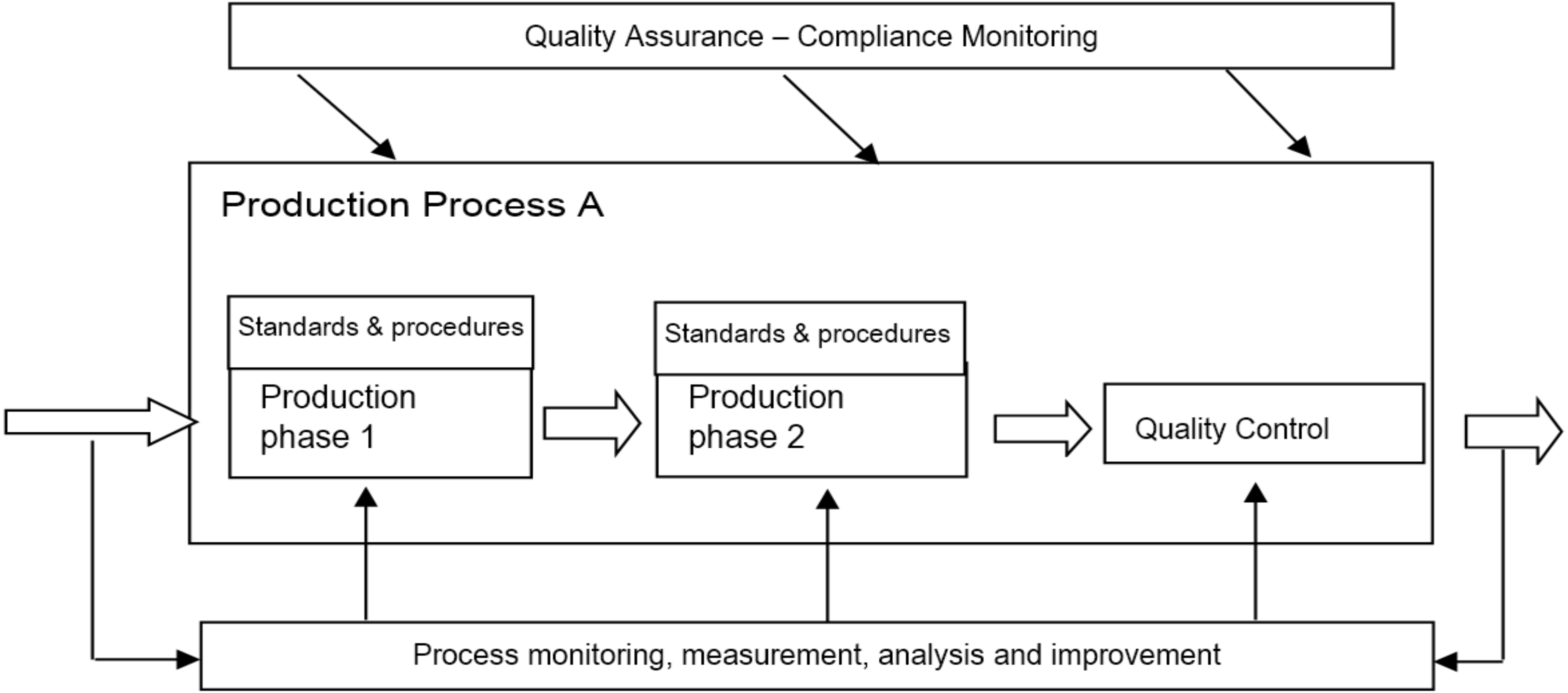
History of Quality Management Development (cont'd)

→ Quality Management Phase



Definitions

- Quality control – a constituent part of quality management directed at fulfilling quality requirements (specifications) through discovery and elimination of nonconformant products
- Quality assurance – a constituent part of quality management whose purpose is to create conditions for ensuring the fulfilment of quality requirements (specifications) by assuring that all prescribed procedures and specifications are appropriate and are complied with
- Quality management – coordinated activities of the management and the organization of the entire company aimed at creating the conditions that will ensure the quality of a product or service

Definitions

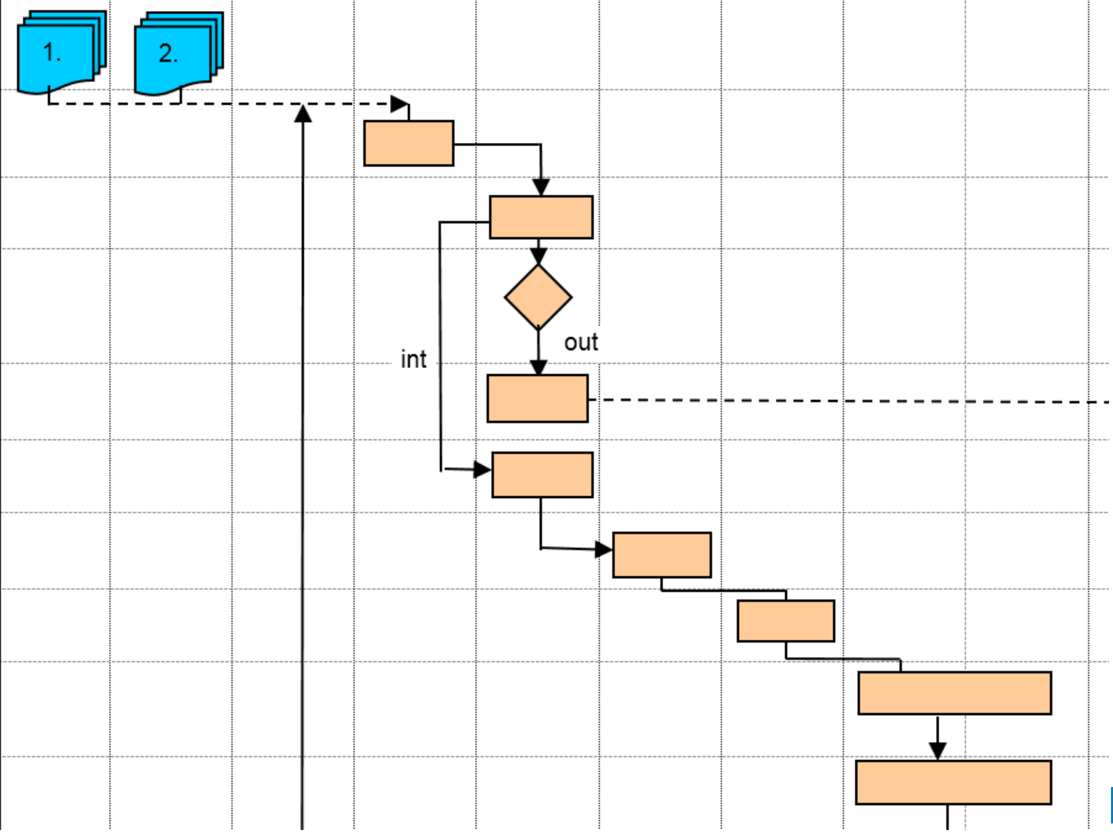
- → Document - information and its supporting medium. The medium can be paper, magnetic, electronic, photograph, etc.
- → Record - document stating result achieved or providing evidence of activities performed.
- → Process - set of inter–related or interacting activities which transforms input into output.
- → Procedure - specified way to carry out an activity or a process.
- → Conformance - fulfillment of a requirement

Definitions

- Audit - systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the "audit criteria" are fulfilled (ORO.GEN.200, ISO9000) or
- *Audit is a systematic and independent comparison of the way in which certain operations are actually carried out and the way in which they are defined in written and published procedures*
- Inspection - independent documented conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging, in order to verify compliance with applicable requirements. (ORO.GEN.200)

Process - Procedure Relationship

No.	PROCESS STEPS	CAA	MANU	QA	ENG	PPC	LOG	HAN. PLAN	MAI
1	Reference Regulations and Maintenance Data	1.	2.						
2	Evaluation of reference documentation, development of Aircraft Maintenance Program								
3	Aircraft Maintenance Planning								
4	Decision: internal work or outsourcing to maintenance provider								
5	Subcontracting of maintenance work								
6	Issuing of work order								
7	Preparation of material and tooling								
8	Planning of hangar workflow								
9	Maintenance work								
10	Certificate of release to service								



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Quality Management Systems

ISO 9000 Family of Standards

ISO 9000

- ISO - International Organization for Standardization
- Founded on 23.Feb.1947 and headquartered in Switzerland, Geneva
- First Quality Standards of ISO9000 family created in 1987
  - To eliminate country to country differences
  - To eliminate terminology confusion
  - To increase quality awareness
- ISO 9001/9004 (Quality Management Systems) is among the most well known and widely implemented ISO standards ever
- Implemented by 1 million organizations in 175 countries.

What is ISO 9001?

- ISO 9001 is a generic and universal standard.
- It is accompanied by ISO9004 – Guidance Material
- Generic and universal means that the same standard can be applied:
  - to any organization, large or small,
  - whatever it is, production or service,
  - in any sector of activity, and
  - whether it is a business enterprise, a public administration, or a government department.

Key Chapters of ISO 9001:2015

- → 5. Context of the Organization
- → 6. Leadership
- → 7. Planning
- → 8. Support
- → 9. Operation
- → 10. Performance Evaluation
- → 11. Improvement

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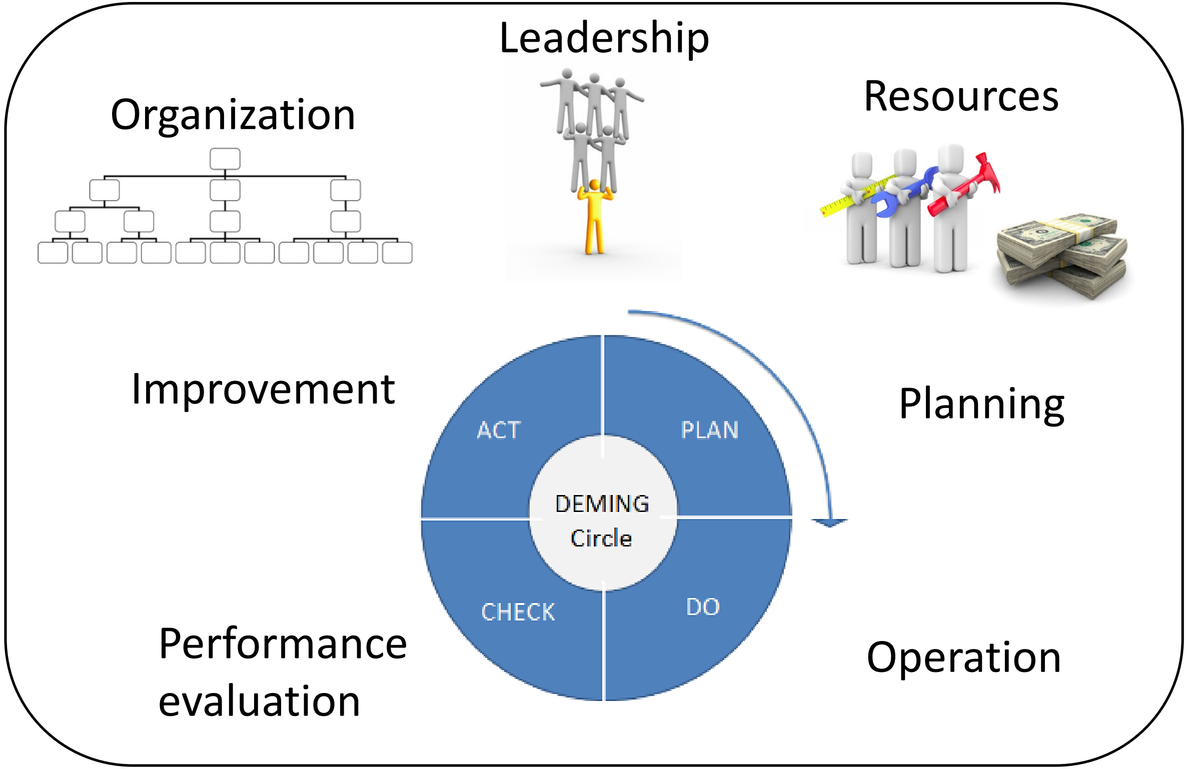
Quality Management Systems

Key Elements of quality management system per ISO9000

Key Elements of Quality Management System



All key elements of QMS have to be in place in order to have functional system!

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Organization

- Understanding the organization & its context (external and internal)
  - External context (international, national, regional or local): legal, technological, competitive, market, cultural, social and economic environments
  - Internal context: values, culture, knowledge and performance of the organization.
- Understanding the needs & expectations of interested parties
  - Example: passengers, customers, Civil Aviation Authority, service provider
- Determining the scope of the QMS
  - The organization shall determine the boundaries and applicability of the quality management system to establish its scope.
  - Example: Part 145 scope of approval
- The QMS and its processes
  - Organization chart
  - Development of necessary and adequate processes and procedures

Leadership

- Top management MUST demonstrate leadership & commitment with the respect to QMS:
  - Top management must fully embrace and enforce QMS:
    - Through establishment of appropriate Quality policy and Quality objectives
    - Through full and unconditional support and compliance to established QMS processes and policies
- Organizational roles, responsibilities & authorities
  - Must be clearly defined on all levels of the organization
  - All activities of the Organization must be covered by adequate assignment of responsibility

Planning

- Definition of planning (one of many):
  The process of setting goals, developing strategies, processes and activities, outlining schedules and allocating resources to accomplish the goals.
- It has to consider and evaluate all requirements and all issues (context!) to determine the risks and opportunities that need to be addressed.

Planning

- Planning starts with quality objectives set by management. Quality objectives should be:
  - Consistent with quality policy
  - Measurable
  - Relevant to conformity of product/service with: regulatory requirements, internally set quality standards and customer expectations
- Planning of changes is mandatory!
  - No major change of any of key QMS elements should be performed without adequate planning and risk assessment
  - Major quality issues may arise out of unplanned changes!

Resources

- Basic resources:
  - People:
    - Adequacy of competence for planned scope of work
    - Adequacy of manpower for the planned volume of work
    - Awareness of existing quality policy, organizational procedures and policies
  - Infrastructure & Equipment
    - Hangars, storage facilities, offices…
    - Equipment, tooling, furniture…
    - IT networks and services
    - Transportation resources
  - Documented Information
    - Manuals and procedures
    - Regulations and regulatory documents
    - Industry standards
    - Records

Finances

Resources (cont'd)

- Environmental considerations
  - social (e.g. non-discriminatory, calm, non-confrontational);
  - psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
  - physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)
- Monitoring and measuring resources
  - Precision and measurement equipment (PME) calibration and maintenance
  - Calibration records and traceability
  - Identification marks and storage/safeguarding
- Organizational knowledge
  - internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
  - external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

Resources (cont'd)

- Communication
  - Organization shall define communication standards covering:
    - Media of communication
    - Timing of communication
    - With whom to communicate
    - How to communicate
    - Who communicates
  - Types of communication:
    - General communication: emails, internal memo's, corporate memo's, minutes of meeting…
    - Process specific communication: accounting reports and forms, operations communications, aircraft log books….
- Outsourcing
  - Reasons for outsourcing:
    - Lack of capacity
    - Lack of capability
    - Economical reasons

Operation

- → Operational planning & control = Planning on „tactical" or operational level
  - → Determine the requirements for the products/services (e.g.. requirements for the performance of flight from a to b: fuel, atc requirements, legal requirements, best flight route, alternate airports, airport limitations, required special equipment, required special pilot's skill/certificate…)
  - → Defining criteria for processes and for acceptance of products/services (e.g.. Max. tail wind for T/O)
  - → Determining of the resources required for conformance of the produce/service
  - → Implementing control of process
  - → determining, maintaining and retaining documented information (records)

Operation

- Requirements for products and services
  - Communication with customers
  - Determining the requirements for products and services
  - Review of the requirements for products and services
  - Changes to requirements for products and services
- Control of externally provided processes, products and services

Operation

- Production and service provision
  - Control of production and service provision
    - The organization shall implement production and service provision under controlled conditions.

      Controlled conditions shall include, as applicable:

      a) the availability of documented information that contains procedures and instructions

      b) the availability and use of suitable monitoring and measuring resources

      c) the implementation of monitoring and measurement activities

      d) the use of suitable infrastructure and environment for the operation of processes

      e) the appointment of competent persons, including any required qualification

      f) the validation, and periodic revalidation, of the ability to achieve planned results of the process

      g) the implementation of actions to prevent human error;

      h) the implementation of release, delivery and post-delivery activities.

Operation

- Identification and traceability
  - The organization shall use suitable means to identify outputs when it is necessary
  - The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
  - The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

Operation

- → Property belonging to customers or external providers
  - → The organization shall exercise care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization.
  - → The organization shall identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services.
  - → When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

Operation

- Preservation
  - The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.
- Post-delivery activities
  - The organization shall meet requirements for post-delivery activities associated with the products and services.

Operation

- Control of changes
  - The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
  - The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Operation

- Release of products and services
  - The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.
  - The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed
  - The organization shall retain documented information on the release of products and services

Operation

- Nonconforming goods & services
  - The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery
  - The organization shall deal with nonconforming outputs in one or more of the following ways:
    - a) correction;
    - b) segregation, containment, return or suspension of provision of products and services;
    - c) informing the customer;
    - d) obtaining authorization for acceptance under concession.
  - The organization shall retain documented information about nonconforming output

Performance Evaluation

- Monitoring, measurement analysis & evaluation
  - The organization shall determine:
    - what needs to be monitored and measured;
    - the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
    - when the monitoring and measuring shall be performed;
    - when the results from monitoring and measurement shall be analyzed and evaluated.
  - The organization shall evaluate the performance and the effectiveness of the quality management system.
  - The organization shall retain appropriate documented information as evidence of the results.

Performance Evaluation

- Customer satisfaction
  - ISO 9001 mandates measurement of customer satisfaction
- Analysis and evaluation
  - The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.
  - The results of analysis shall be used to evaluate:
    - conformity of products and services;
    - the degree of customer satisfaction;
    - the performance and effectiveness of the quality management system;
    - if planning has been implemented effectively;
    - the effectiveness of actions taken to address risks and opportunities;
    - the performance of external providers;
    - the need for improvements to the quality management system.

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Performance Evaluation – Internal Audit

- The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
  - conforms to internal and external requirements
  - is effectively implemented and maintained
- The organization shall:
  - plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - define the audit criteria and scope for each audit;
  - select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
  - ensure that the results of the audits are reported to relevant management;
  - take appropriate correction and corrective actions without undue delay;
  - retain documented information as evidence of the implementation of the audit program and the audit results.

Performance Evaluation - Management Review

- Top management shall review the organization’s quality management system at planned intervals.
- Management review inputs
  - the status of actions from previous management reviews;
  - changes in external and internal issues that are relevant to the quality management system;
  - information on the performance and effectiveness of the quality management system, including trends in:
    - customer satisfaction and feedback from relevant interested parties;
    - the extent to which quality objectives have been met;
    - process performance and conformity of products and services;
    - nonconformities and corrective actions;
    - monitoring and measurement results;
    - audit results;
    - the performance of external providers

Performance Evaluation - Management Review

- the adequacy of resources;
- the effectiveness of actions taken to address risks and opportunities (see 6.1);
- opportunities for improvement.
- The outputs of the management review shall include decisions and actions related to:
  - opportunities for improvement;
  - any need for changes to the quality management system;
  - resource needs.
- The organization shall retain documented information as evidence of the results of management reviews.

Improvement

- The organization shall determine and select opportunities for improvement and implement any necessary actions to meet defined requirements. These shall include:
  - improving products and services to meet requirements as well as to address future needs and expectations;
  - correcting, preventing or reducing undesired effects;
  - improving the performance and effectiveness of the quality management system.

Improvement

- Nonconformity and corrective action
  - When a nonconformity occurs the organization shall:
    - react to the nonconformity and take action to control and correct it
    - evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere;
    - implement any action needed;
    - review the effectiveness of any corrective action taken;
    - update risks and opportunities determined during planning;
    - make changes to the quality management system, if necessary.
  - Corrective actions shall be appropriate to the effects of the nonconformities encountered.
  - The organization shall retain related documented information as evidence

Improvement

- Major nonconformity:
  - Any violation which shows a gap in system or an ultimate fail in quality of the product,

    or
  - System element is: missing, not implemented or not effective

Improvement

- Minor non-conformity:
  - Partial lack in quality system which has no direct impact on product quality or
  - A single/isolated lapse in the system

- Observation:
  - The cause of a potential non-conformity or other undesirable situation which needs improvement

Improvement

- Continual improvement
  - The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

European Union Aviation Safety Agency

Quality Management Systems

Roles and Responsibilities within the QMS

Roles & Responsibilities

- Within the quality management system we have three typical roles at the level of management:
  - Accountable manager, CEO, General Manager, Director General…
  - Quality Manager
  - Postholder, Nominated person, Responsible person, Manager

Roles & Responsibilities

- Accountable manager:
  - Has full executive and unrestrained power within the organization,
  - Has overall responsibility for management system and functioning of the Organization.
  - Is ultimately responsible that all identified nonconformance's are remedied in satisfactory and timely manner.
  - In small organization can also have the role of postholder/nominated person, depending on his qualifications, but can not have role of quality manager.

Roles & Responsibilities

Quality Manager

- Monitors functioning of whole Quality Management System, is responsible that there is functional audit system in place and that noncompliance's are identified, recorded, assessed and reported to responsible managers.
- Is independent in relation to any postholder/nominated person and does not have conflict of interest.
- Reports to postholders/nominated persons and other responsible managers about nonconformance's identified within their area of responsibility and monitors that corrective actions are performed.

Roles & Responsibilities

- Is directly subordinated to Accountable manager and reports to Accountable Manager about:
  - overall results of Audit process,
  - identified nonconformance's and corrective actions taken by responsible managers
  - all issues and problems related to quality

Roles & Responsibilities

- Postholder/Nominated Person
  - Is manager who manages and is responsible for certain area of activities (e.g.. Flight Operations, Maintenance…)
  - Is subordinated and reports to Accountable manager.
  - With regards to QMS, he is responsible that his organizational unit/s performs activities in accordance with quality policy, prescribed procedures and other applicable requirements (e.g.. Regulatory).
  - Is responsible for timely performance of appropriate corrective actions to remedy all nonconformance's identified in his area of responsibility.
  - Can not be Quality Manager

End of presentation

Thank you for your attention!

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ARISE+
Funded by the European Union and implemented by the European Union Aviation Safety Agency

ICAO and EASA Regulatory Framework for Aircraft Maintenance Programs

Omer Pita and Salvador Alepuz
Airworthiness Experts

Your safety is our mission.

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EASA
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ARISE+
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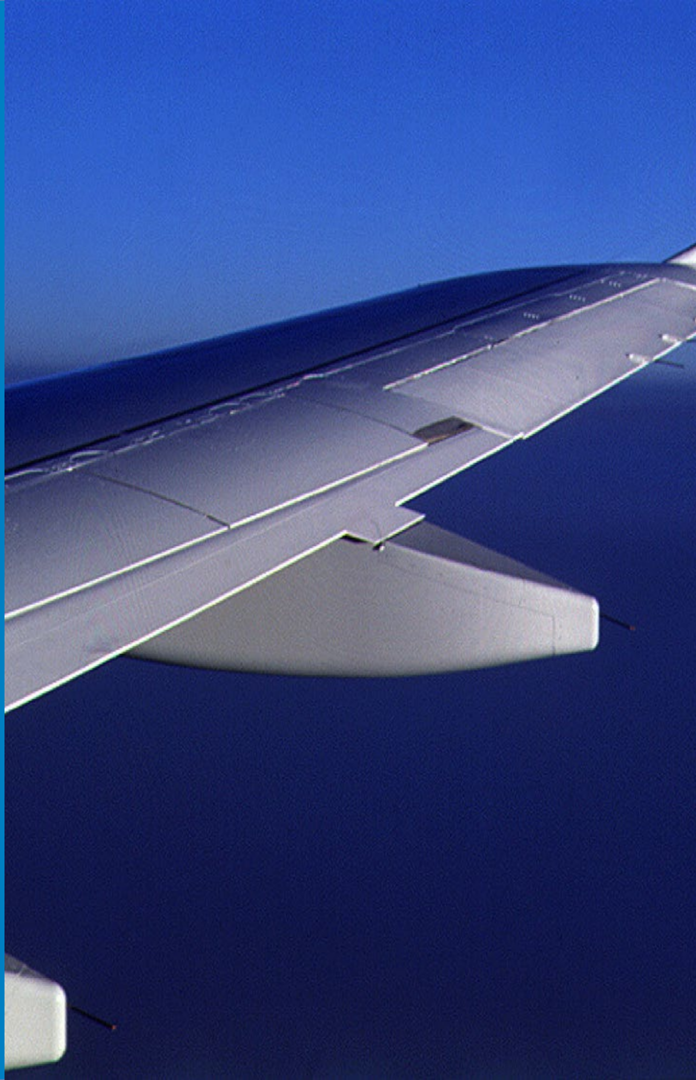
International Regulatory Bodies and Their Regulations



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International Civil Aviation Organization ICAO

- The International Civil Aviation Organization (ICAO) is a specialized agency of the United Nations.
- It defines international civil aviation standards and recommended practices
- Its headquarters are located in Montreal, Canada.
- It has been established by the Convention on International Civil Aviation, also known as the Chicago Convention, in Chicago, Illinois, on 7 December 1944.
- ICAO begun its operations on 4 April 1947, and in October 1947, ICAO became an agency of the United Nations linked to the United Nations Economic and Social Council (ECOSOC)

ICAO (cont’d

- ICAO has seven regional offices, and one regional sub-office:
  - Asia and Pacific (APAC) – Bangkok, Thailand;
    - Sub-office – Beijing, China
  - Eastern and Southern African (ESAF) – Nairobi, Kenya
  - Europe and North Atlantic (EUR/NAT) – Paris, France
  - Middle East (MID) – Cairo, Egypt
  - North American, Central American and Caribbean (NACC) – Mexico City, Mexico
  - South American (SAM) – Lima, Peru
  - Western and Central African (WACAF) – Dakar, Senegal

ICAO (cont'd

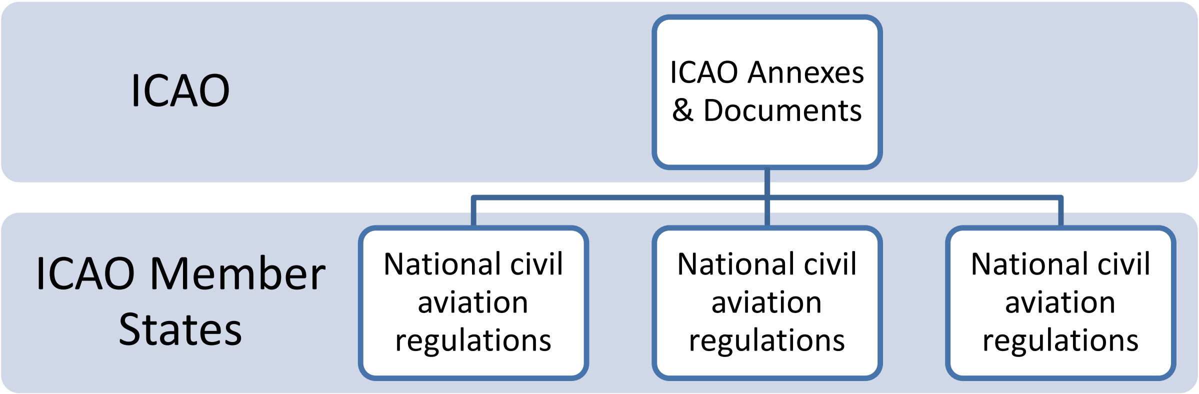
- ICAO publishes its standards and recommended practices predominantly through:
  - Annexes to the Chicago Convention (19 Annexes published so far)
  - ICAO DOC's
- The Annexes are:
  - Annex 1 - Personnel Licensing
  - Annex 2 - Rules of the Air
  - Annex 3 - Meteorological Services
  - Annex 4 - Aeronautical Charts
  - Annex 5 - Units of Measurement
  - Annex 6 - Operation of Aircraft
  - Annex 7 - Aircraft Nationality and Registration Marks
  - Annex 8 - Airworthiness of Aircraft

ICAO (cont'd)

- Annex 9 - Facilitation
- Annex 10 - Aeronautical Telecommunications
- Annex 11 - Air Traffic Services
- Annex 12 - Search and Rescue
- Annex 13 - Aircraft Accident and Incident Investigation
- Annex 14 - Aerodromes
- Annex 15 - Aeronautical Information Services
- Annex 16 - Environmental Protection
- Annex 17 - Security
- Annex 18 - The Safe Transportation of Dangerous Goods by Air
- Annex 19 - Safety management

ICAO (cont'd)

- ICAO Member states (UN members) have legal obligation to align national civil aviation regulations in accordance with ICAO standards



- ICAO is setting global civil aviation standards which enable seamless international civil aviation operations

National Civil Aviation Authorities

- Chicago Convention with its Annexes is also requesting each member state to establish and empower its national Civil Aviation Authority as a sole body within the government system responsible for national civil aviation.
- National CAA:
  - Are responsible for all aspects of civil aviation but with major focus on civil aviation safety
  - Have high level of autonomy within the government in deciding about aviation safety matters
  - Have, among others, following important duties and responsibilities: rulemaking, certification of organizations and products, licensing of personnel and aviation safety oversight

National Civil Aviation Authorities (cont'd)

- Historically, there are a few national civil authorities that shaped the civil aviation world today.
- US FAA is probably the most prominent national civil authority in the world.
- Many nations in the world use FAA or EASA regulations as basis for their national regulations

European Aviation Safety Agency EASA

- The European Aviation Safety Agency (EASA) is
  an agency of the European Union (EU) with
  regulatory and executive tasks in the field of civil aviation safety.
- It is based in Cologne, Germany.
- The EASA was created on 15 July 2003 and it reached full functionality in 2008, taking over functions of the former Joint Aviation Authorities (JAA).
- The legal position of EASA is unique due to the fact that EASA is rulemaker for EU and also does product certification (TC) for all EU members, but is not national authority and therefore is not represented as member state in ICAO.
- National authorities of EU member states have partial certification (no TC) function and oversight function within their countries.

EASA (cont'd)

→ EASA carries out audits of the EU Member States NAA under standardization program with aim to standardize EU NAA certification and oversight standards.

→ EASA also launched quite successful SAFA (Safety Assessment of Foreign Aircraft) inspection program which is gaining popularity worldwide, as more and more countries join the program.

→ Internationally, EASA regulations are increasingly taken as raw model for national aviation regulations by many non-EU states.

Other non-governmental international organizations

- There is a number of national and international civil aviation organizations and associations that are representing different branches of civil aviation industry and that are setting industry standards which are voluntary accepted worldwide.
- Most prominent are: IATA, A4A (former ATA), SAE, FSF…
- These organizations are strong industry associations with large membership having capability to set industry standards and contribute to rulemaking efforts of governmental organizations like ICAO, FAA, EASA and other.
- Example of widely accepted industry standard is IOSA (IATA Operational Safety Audit) program launched by IATA and widely used by international airlines.

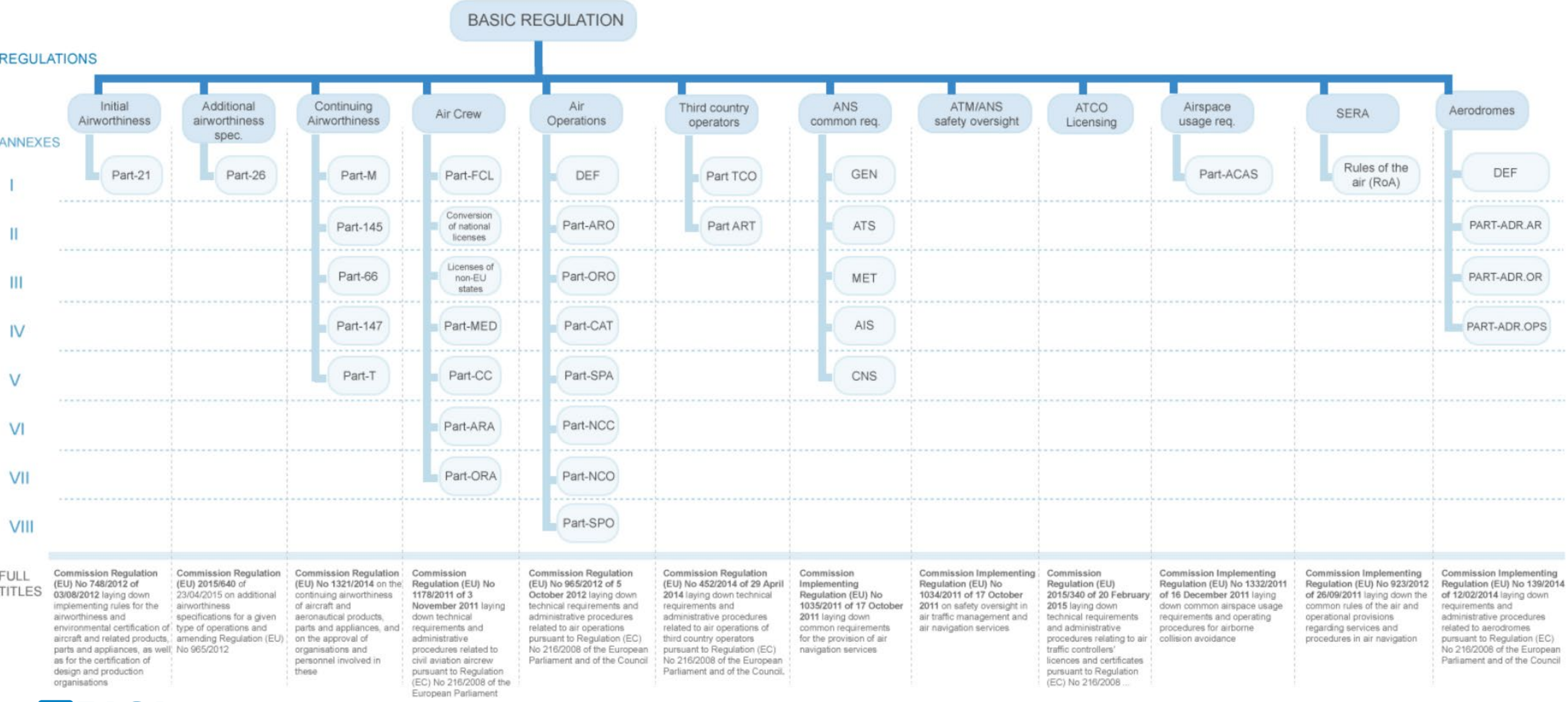
About Rulemaking Procedure in EU

- EASA – the European Aviation Safety Agency using NPA (Notice of Proposed Amendment) process creates a draft to a legislation which is intended to be applied throughout the European Member States
- The European Commission releases the work of the Agency in the form of a Commission Regulation or Directive, by means of which the contents of that work actually become binding law within the European Union
  - Commission Regulation applies directly within EU
  - Commission Directive gives essential content of regulation which has to be regulated by each Member State in national regulations (indirect application)

About Rulemaking Procedure in EU

- The Member States, if necessary, must adjust their national regulations to allow for direct implementation of the Commission Regulation or, in case of Commission Directive, Member States have to enact national regulation to implement the Directive.
- EASA creates and enacts „soft law” based on above EU Regulations in form of AMC (Acceptable Means of Compliance), GM (Guidance Material) and CS (Certification Specifications).

Structure of EU (EASA) Regulations



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Structure of EU (EASA) Regulations

„Hard law" – Commission Regulation

Air Operations

Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council.

Show regulations

Acceptable Means of Compliance and Guidance Material

GM to the Cover Regulation	DEF	Part-ARO
Part-ORO	Part-CAT	Part-SPA
Part-NCC	Part-NCO	Part-SPO

Certification Specification

CS-FSTD(A)	CS-FSTD(H)	CS-FTL.1

„Soft law" – GM, AMC and CS

DEF= Definitions; ARO=Authority Requirements; ORO=Organizational Requirements; CAT=Commercial Transport Requirements; SPA=Special Performance Approvals; NCC=Non-commercial, complex aircraft; NCO=Non-commercial, non-complex aircraft; SPO=Special Operations (like aerial work)

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Structure of EU (EASA) Regulations

„Hard law” – Commission Regulation

Continuing Airworthiness

Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks

Show regulations

Easy Access Rules: Continuing Airworthiness (Regulation (EU) No 1321/2014)

Acceptable Means of Compliance and Guidance Material

Part-M	Part-145	Part-66
Part-147	Part-T	

„Soft law” – GM, AMC and CS

EASA

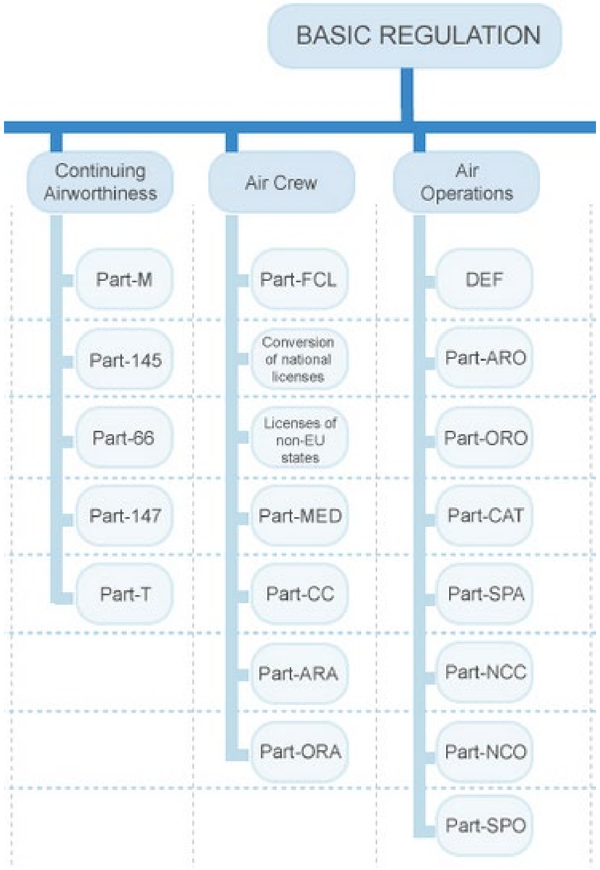
EASA AMC, GM & CS

- Even though it is a „soft law", meaning it is not obligatory, in EU is compliance with AMC, GM and CS considered to be mandatory, unless applicant for certificate is not ready to develop and „defend" Alternative Means of Compliance which he has to present to certifying Authority.
- All major EU aviation safety regulations can be downloaded in consolidated form from EASA website: (*https://www.easa.europa.eu/document-library/technical-publications*)

Core EU Regulations for Airline Operations and Maintenance

→ Example of regulations applicability:

- Airlines (commercial air transport):
  - Basic Regulation
  - Air Operations Regulation
  - Part-CAT (requirements for commercial operations)
  - Part-ORO (organisational requirements)
  - Part-SPA (specific approvals - PBN, RVSM, MNPS, LVO…)
- Airlines CAMO & standalone CAMO organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-M
- Maintenance organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-145
- Maintenance training organisations:
  - Basic Regulation
  - Continuing Airworthiness Regulation
  - Part-147
  - Part-66



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Terminology Differences in EU Regulations

- Terminology used in different EU regulations is not consistent. Mostly due to historical reasons.
- Examples:

Part-OPS	Part-145	Part-M	Part-147
Management System (includes SMS)	Quality System (includes Safety Policy)	Quality System	Quality System
Compliance Monitoring Programme	Independent Audit (Process)	Independent Audit (Process)	Independent Audit (Process)
Compliance Monitoring Manager	Quality Manager	Quality Manager	Quality Manager
Compliance Monitoring	Quality Compliance Monitoring	Compliance Monitoring	-
Schedule of Monitoring Programme	Audit Plan	Quality Plan	Scheduled Plan

Contents of EASA Part-M

- Annex I (Part-M)
  - GENERAL
  - SECTION A — TECHNICAL REQUIREMENTS
  - SECTION B — PROCEDURE FOR COMPETENT AUTHORITIES
  - APPENDICES TO ANNEX I (Part-M)
  - APPENDICES TO AMCs AND GM TO ANNEX I (Part-M)

Contents of EASA Part-M

- SUBPART A — GENERAL
  - M.A.101 Scope
- SUBPART B — ACCOUNTABILITY
  - M.A.201 Responsibilities
    - GM M.A.201 Responsibilities
    - GM M.A.201(e) Responsibilities
    - AMC M.A.201(e)(2) Responsibilities
    - GM M.A.201(f) Commercial ATO
    - GM M.A.201(i), M.A.302(h) and M.A.901(l)
    - GM M.A.201(i) Aircraft maintenance programme
    - AMC M.A.201(i)(3) Responsibilities
  - M.A.202 Occurrence reporting

Contents of EASA Part-M

- SUBPART C — CONTINUING AIRWORTHINESS
  - M.A.301 Continuing airworthiness tasks
  - M.A.302 Aircraft Maintenance Programme
  - M.A.303 Airworthiness directives
  - M.A.304 Data for modifications and repairs
  - M.A.305 Aircraft continuing airworthiness record system
  - M.A.306 Aircraft technical log system
  - M.A.307 Transfer of aircraft continuing airworthiness records

Contents of EASA Part-M

- SUBPART D — MAINTENANCE STANDARDS
  - M.A.401 Maintenance data
    - AMC M.A.401 Maintenance data
  - M.A.402 Performance of maintenance
    - AMC M.A.402 Performance of maintenance
    - GM M.A.402 Performance of maintenance
  - M.A.403 Aircraft defects
    - AMC M.A.403 Aircraft defects

Contents of EASA Part-M

- SUBPART E — COMPONENTS
  - M.A.501 Installation
    - AMC M.A.501(a) Installation
  - M.A.501(b) Installation
  - M.A.502 Component maintenance
    - AMC M.A.502 Component maintenance
  - M.A.503 Service life limited components .
  - M.A.504 Control of unserviceable components
    - AMC M.A.504(a) Control of unserviceable components

Contents of EASA Part-M

- SUBPART F — MAINTENANCE ORGANISATION
  - M.A.601 Scope
  - M.A.602 Application
  - M.A.603 Extent of approval
  - M.A.604 Maintenance organisation manual
  - M.A.605 Facilities
  - M.A.606 Personnel requirements
  - M.A.607 Certifying staff and airworthiness review staff
  - M.A.608 Components, equipment and tools
  - M.A.609 Maintenance data
  - M.A.610 Maintenance work orders
  - M.A.611 Maintenance standards
  - M.A.612 Aircraft certificate of release to service
  - M.A.613 Component certificate of release to service
  - M.A.614 Maintenance and airworthiness review records
  - M.A.615 Privileges of the organisation
  - M.A.616 Organisational review
  - M.A.617 Changes to the approved maintenance organisation
  - M.A.618 Continued validity of approval
  - M.A.619 Findings

Contents of EASA Part-M

- SUBPART G — CONTINUING AIRWORTHINESS MANAGEMENT ORGANISATION
  - M.A.701 Scope
  - M.A.702 Application
  - M.A.703 Extent of approval
  - M.A.704 Continuing airworthiness management exposition
  - M.A.705 Facilities
  - M.A.706 Personnel requirements
  - M.A.707 Airworthiness review staff
  - M.A.708 Continuing airworthiness management
  - M.A.709 Documentation
  - M.A.710 Airworthiness review
  - M.A.711 Privileges of the organisation
  - M.A.712 Quality system
  - M.A.713 Changes to the approved continuing airworthiness organisation
  - M.A.714 Record-keeping
  - M.A.715 Continued validity of approval
  - M.A.716 Findings

Contents of EASA Part-M

- SUBPART H — CERTIFICATE OF RELEASE TO SERVICE — CRS
  - M.A.801 Aircraft certificate of release to service
  - M.A.802 Component certificate of release to service
  - M.A.803 Pilot-owner authorisation

Contents of EASA Part-M

- SUBPART I — AIRWORTHINESS REVIEW CERTIFICATE
  - M.A.901 Aircraft airworthiness review
  - M.A.902 Validity of the airworthiness review certificate
  - M.A.903 Transfer of aircraft registration within the EU
  - M.A.904 Airworthiness review of aircraft imported into the EU
  - M.A.905 Findings

ICAO Annex 6

- → CHAPTER 8. Aeroplane maintenance
  - → 8.1 Operator’s maintenance responsibilities
  - → 8.2 Operator’s maintenance control manual
  - → 8.3 Maintenance programme
  - → 8.4 Maintenance records
  - → 8.5 Continuing airworthiness information
  - → 8.6 Modifications and repairs
  - → 8.7 Approved maintenance organization
  - → 8.8 Maintenance release

EASA

ICAO Annex 6

- CHAPTER 11. Manuals, logs and records
  - 11.1 Flight manual
  - 11.2 Operator’s maintenance control manual
  - 11.3 Maintenance programme
  - 11.4 Journey log book
  - 11.5 Records of emergency and survival equipment carried
  - 11.6 Flight recorder records
- ICAO DOC 9760, ICAO DOC 9734

Maintenance Program Requirements

EASA Part M - M.A.302 Aircraft Maintenance Programme

- (a) Maintenance of each aircraft shall be organised in accordance with an aircraft maintenance programme.
- (b) The aircraft maintenance programme and any subsequent amendments shall be approved by the competent authority.

EASA Part M - M.A.302 Aircraft Maintenance Programme

- (c) When the continuing airworthiness of the aircraft is managed by a continuing airworthiness management organisation approved in accordance with Section A, Subpart G of this Annex (Part-M) or when there is a limited contract between the owner and this organisation in accordance with point M.A.201(i)(3), the aircraft maintenance programme and its amendments may be approved through an indirect approval procedure.
  - (i) In that case, the indirect approval procedure shall be established by the continuing airworthiness management organisation as part of the Continuing Airworthiness Management Exposition and shall be approved by the competent authority responsible for that continuing airworthiness management organisation.
  - (ii) The continuing airworthiness management organisation shall not use the indirect approval procedure when this organisation is not under the oversight of the Member State of Registry, unless an agreement exists in accordance with point M.1, paragraph 4(ii), transferring the responsibility for the approval of the aircraft maintenance programme to the competent authority responsible for the continuing airworthiness management organisation.

EASA Part M - M.A.302 Aircraft Maintenance Programme

- (d) The aircraft maintenance programme must establish compliance with:
  - (i) instructions issued by the competent authority;
  - (ii) instructions for continuing airworthiness:
    - issued by the holders of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval issued under Regulation (EU) No 748/2012 and its Annex I (Part-21), and
    - included in the certification specifications referred to in point 21A.90B or 21A.431B of Annex I (Part-21) to Regulation (EU) No 748/2012, if applicable;
  - (iii) additional or alternative instructions proposed by the owner or the continuing airworthiness management organisation once approved in accordance with point M.A.302, except for intervals of safety related tasks referred in point (e), which may be escalated, subject to sufficient reviews carried out in accordance with point (g) and only when subject to direct approval in accordance with point M.A.302(b).

EASA Part M - M.A.302 Aircraft Maintenance Programme

- (e) The aircraft maintenance programme shall contain details, including frequency, of all maintenance to be carried out, including any specific tasks linked to the type and the specificity of operations.
- (f) For complex motor-powered aircraft, when the maintenance programme is based on maintenance steering group logic or on condition monitoring, the aircraft maintenance programme shall include a reliability programme.
- (g) The aircraft maintenance programme shall be subject to periodic reviews and amended accordingly when necessary. These reviews shall ensure that the programme continues to be valid in light of the operating experience and instructions from the competent authority whilst taking into account new and/or modified maintenance instructions promulgated by the type certificate and supplementary type certificate holders and any other organisation that publishes such data in accordance with Annex I (Part-21) to Regulation (EU) No 748/2012.

EASA Part M - M.A.302 Aircraft Maintenance Programme

- The term ‘maintenance programme’ is intended to include scheduled maintenance tasks the associated procedures and standard maintenance practises. The term ‘maintenance schedule’ is intended to embrace the scheduled maintenance tasks alone.
- The aircraft should only be maintained to one approved maintenance programme at a given point in time. Where an owner or operator wishes to change from one approved programme to other, a transfer check or inspection may need to be performed in order to implement the change.
- The maintenance programme details should be reviewed at least annually. As a minimum revisions of documents affecting the programme basis need to be considered by the owner or operator for inclusion in the maintenance programme during the annual review. Applicable mandatory requirements for compliance with Part-21 should be incorporated into the aircraft maintenance programme as soon as possible.

EASA Part M - M.A.302 Aircraft Maintenance Programme

- The aircraft maintenance programme should contain a preface which will define the maintenance programme contents, the inspection standards to be applied, permitted variations to task frequencies and, where applicable, any procedure to manage the evolution of established check or inspection intervals.
- Repetitive maintenance tasks derived from modifications and repairs should be incorporated into the approved maintenance programme.
- Appendix I to AMC M.A.302 provides detailed information on the contents of an approved aircraft maintenance programme.

EASA Part M - GM M.A.302(a) Aircraft Maintenance Programme

- A maintenance programme may indicate that it applies to several aircraft registrations as long as the maintenance programme clearly identifies the effectivity of the tasks and procedures that are not applicable to all of the listed registrations.

EASA Part M - AMC M.A.302(d) Aircraft maintenance programme

→ An aircraft maintenance programme should normally be based upon the maintenance review board (MRB) report where applicable, the maintenance planning document (MPD), the relevant chapters of the maintenance manual or any other maintenance data containing information on scheduling. Furthermore, an aircraft maintenance programme should also take into account any maintenance data containing information on scheduling for components.

EASA Part M - AMC M.A.302(d) Aircraft maintenance programme

- Instructions issued by the competent authority can encompass all types of instructions from a specific task for a particular aircraft to complete recommended maintenance schedules for certain aircraft types that can be used by the owner/operator directly. These instructions may be issued by the competent authority in the following cases:
  - in the absence of specific recommendations of the Type Certificate Holder.
  - to provide alternate instructions to those described in the subparagraph 1 above, with the objective of providing flexibility to the operator.

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EASA Part M - AMC M.A.302(d) Aircraft maintenance programme

- Where an aircraft type has been subjected to the MRB report process, an operator should normally develop the initial aircraft maintenance programme based upon the MRB report.
- Where an aircraft is maintained in accordance with an aircraft maintenance programme based upon the MRB report process, any associated programme for the continuous surveillance of the reliability, or health monitoring of the aircraft should be considered as part of the aircraft maintenance programme.

EASA Part M - AMC M.A.302(d) Aircraft maintenance programme

- Aircraft maintenance programmes for aircraft types subjected to the MRB report process should contain identification cross reference to the MRB report tasks such that it is always possible to relate such tasks to the current approved aircraft maintenance programme. This does not prevent the approved aircraft maintenance programme from being developed in the light of service experience to beyond the MRB report recommendations but will show the relationship to such recommendations.

EASA Part M - AMC M.A.302(d) Aircraft maintenance programme

- Some approved aircraft maintenance programmes, not developed from the MRB process, utilise reliability programmes. Such reliability programmes should be considered as a part of the approved maintenance programme.
- Link to EASA Requirements

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Introduction to Reliability Programs

Omer Pita and Salvador Alepuz
Airworthiness Experts

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Course Contents

- → Reliability in general
- → Maintenance reliability program – definitions
- → Process flow of a reliability program
- → Organizational structure of a reliability program
- → Reliability performance parameters or indicators
- → Alert values
- → Reliability Report
- → Corrective Actions

Reliability

- MIL definition:

  Reliability is **the probability** that an item will perform a required function without failure under stated conditions for a stated period of time.

- Supplement to the definition of reliability in the context of the maintenance reliability program:

  Reliability is a measure of the performance stability of the aircraft systems, its components and operational&maintenance processes.

  Aircraft system or aircraft component is considered to be reliable if its operational performance is falling within designed and/or expected parameters.

There is a difference in reliability between different aircraft types

- F104 Starfighter (German version) – 269 accidents (out of total 960) and 110 killed pilots on that aircraft type in the German Luftwaffe
- F104 – American version operated in US Air Force has several times better safety record.
- Why?

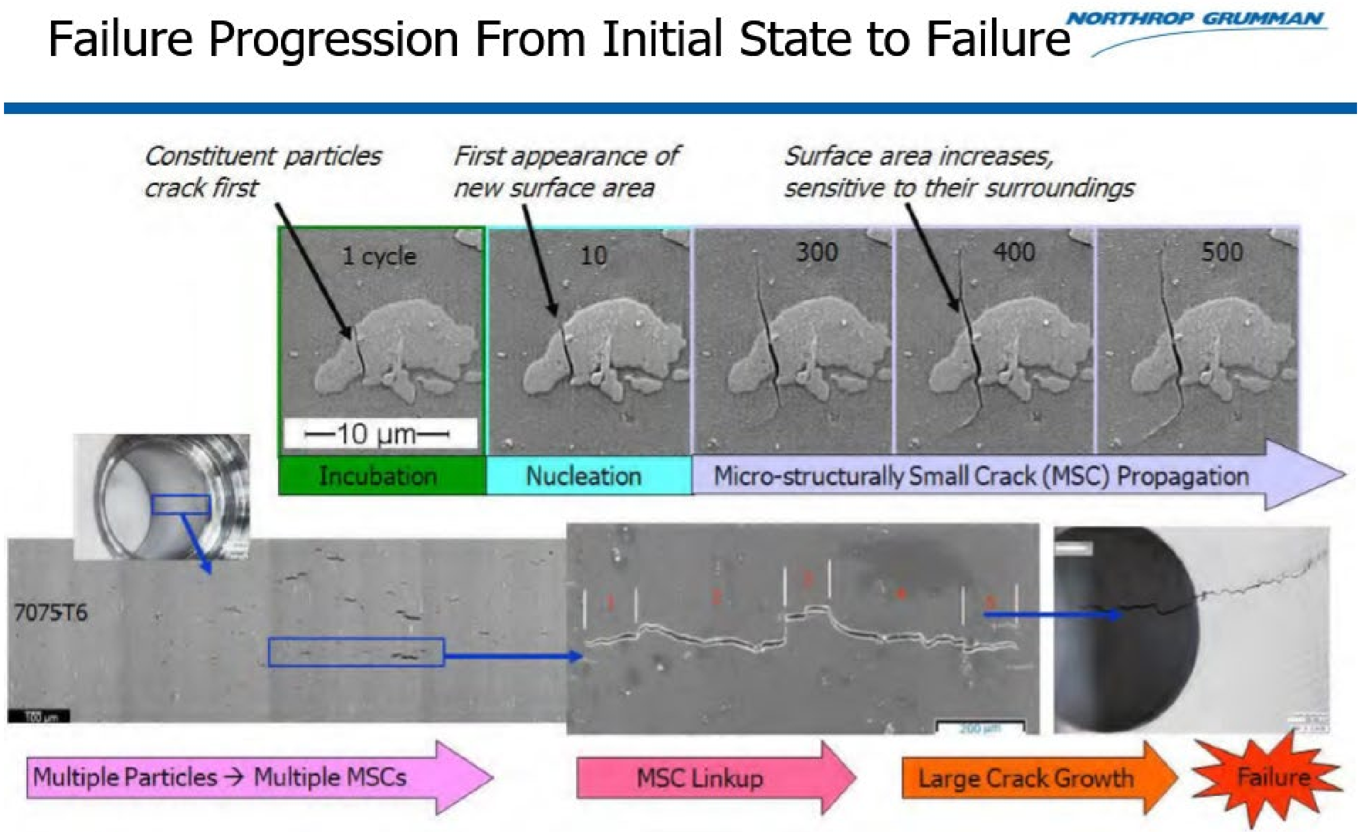
Differences in reliability

- F4 Phantom - 27 accidents on more than 1.000.000 flights in German Luftwaffe (ten times better safety record compared to F104)
- Why?

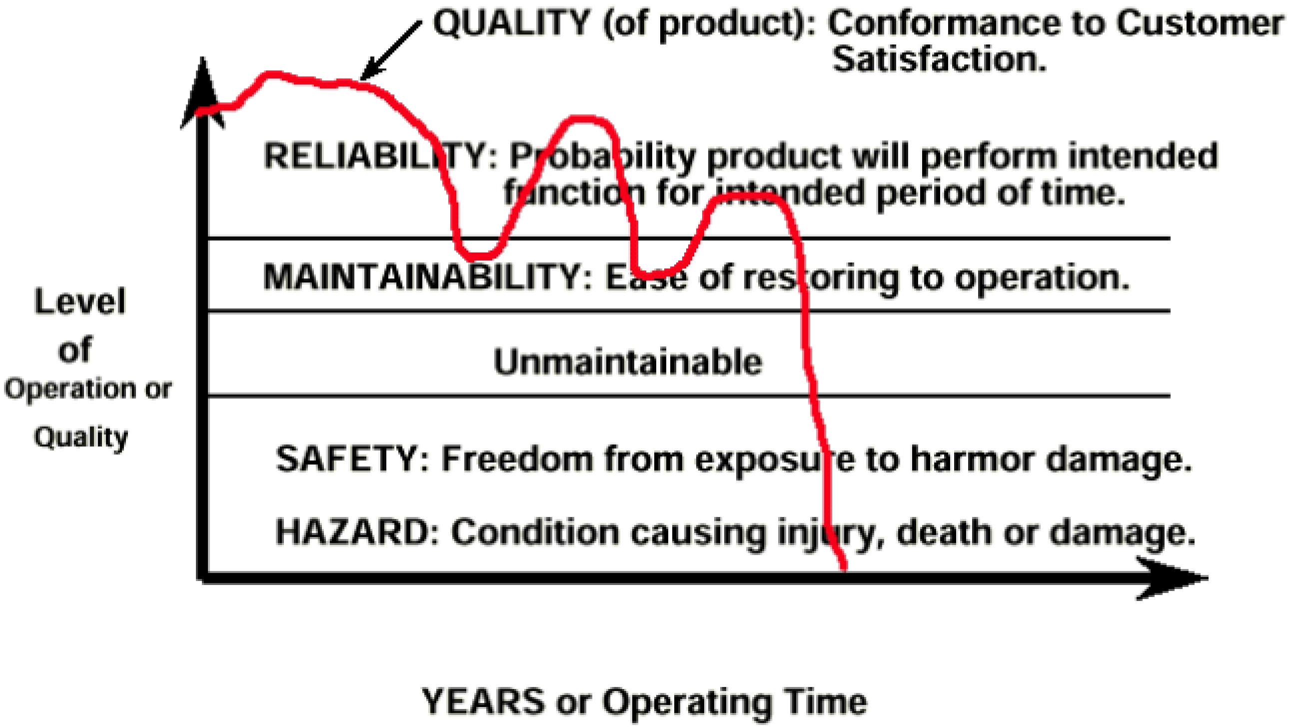
Sources of Aircraft System Failures

- Design
  - specified inadequate tolerances (eg. insufficient clearances between parts)
  - Not having adequate understanding of the operational environment
  - Inadequate testing – unconfirmed design
  - Insufficient understanding of the component reliability
- Production
  - Inappropriate replacements for specified materials
  - Production process ommissions or production procedures not followed
  - Contamination
  - Wrong thermal treatment of metals
- Operation and Maintenance
  - Aircraft loads outside of certified limits
  - Operation in the non certified environment
  - Maintenance not in accordance with prescribed procedures

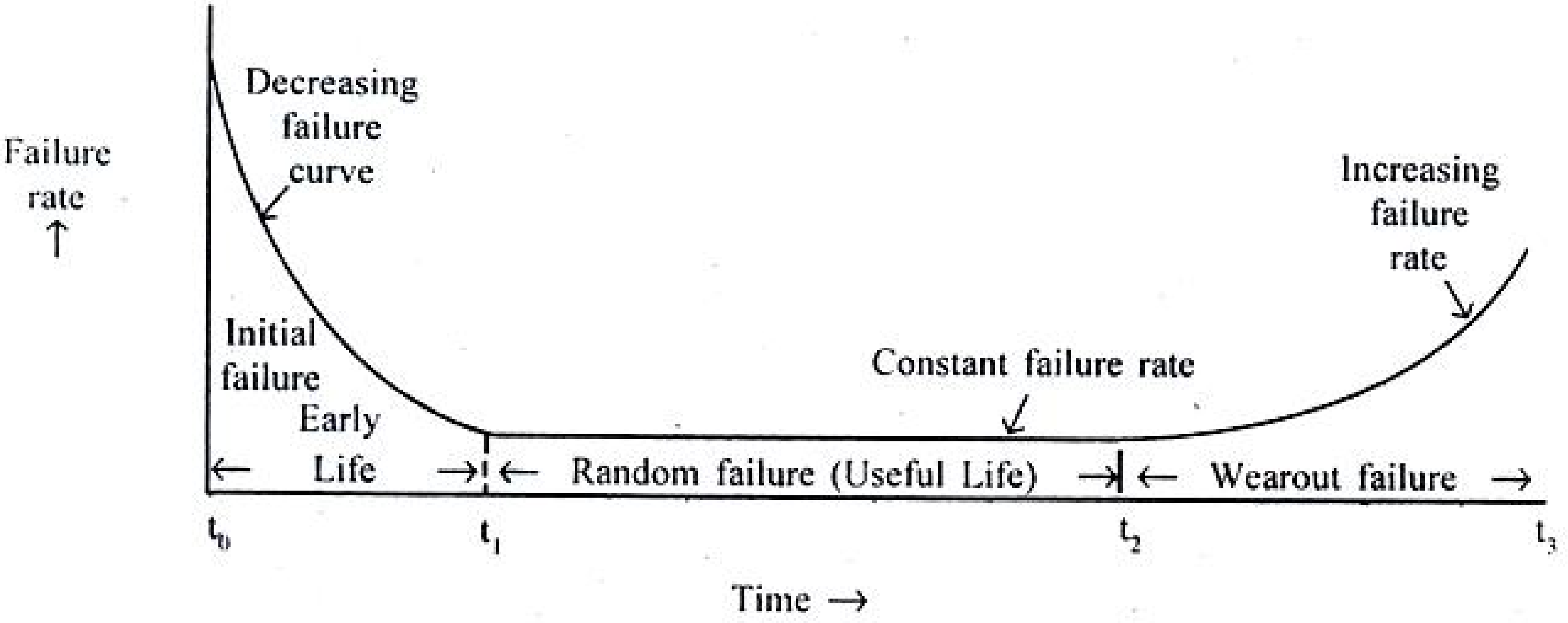
Design – understanding the crack propagation



RELATIONSHIP:
QUALITY -- RELIABILITY-- SAFETY



Reliability of components and systems – bathtub curve

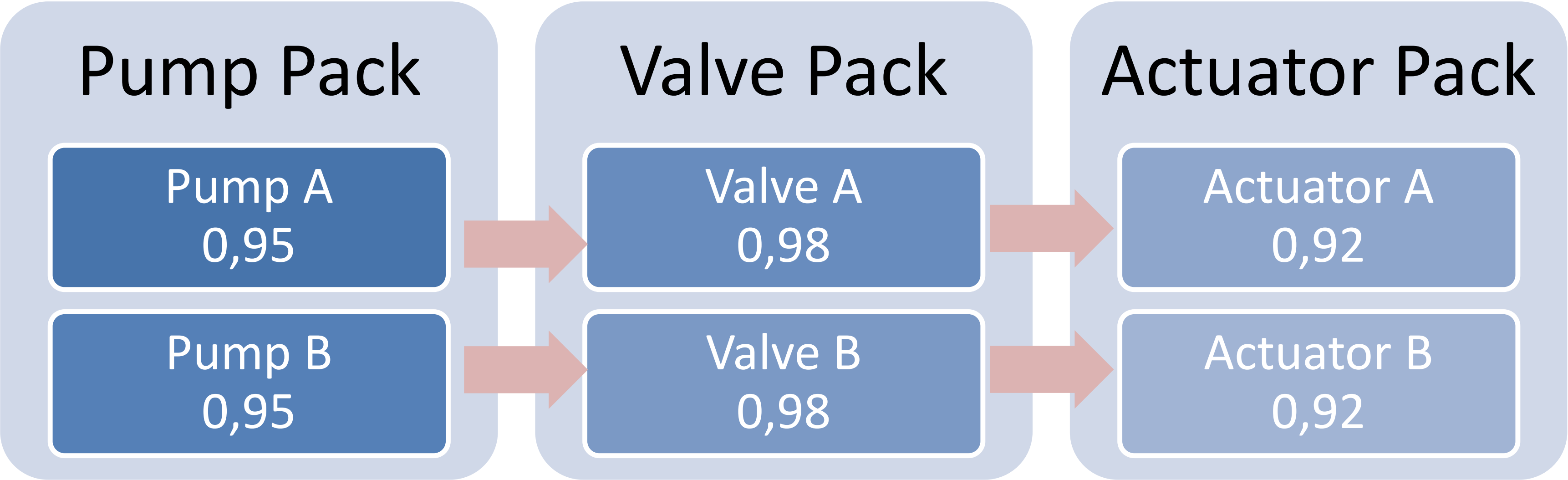


Reliability of the system with components interconnected in the series

$$R(system) = R(pump) \cdot R(valve) \cdot R(actuator)$$

$$R(system) = 0{,}95 \cdot 0.98 \cdot 0{,}92 = \mathbf{0,86}$$

Reliability of the System with components interconnected in parallel



$$R(pump\ pack) = 1 - [1 - R(pumpA)] \cdot [1 - R(pumpB)]$$

$$R(pump\ pack) = 1 - [1 - 0{,}95] \cdot [1 - 0{,}95] = 0{,}9975$$

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- Let us calculate the reliability of the whole system!

Maintenance Reliability Program

- Maintenance Reliability Program is a system of data collection, statistical analysis and reporting of the events related to the technical status of the fleet during the operation of the aircraft/aircraft type in an operator’s fleet.
- Since the operation widely varies between operators, reliability program is carried on by the each operator on it’s fleet with the aim to analyze his specific operation.
- Primary purpose of the Reliability Program is to provide information that is needed to adjust and improve operator’s Aircraft Maintenance Program for the aircraft/aircraft type operated in it’s fleet.

Maintenance Reliability Program

- Reliability Program provides insight in the reliability of the overall operation of the aircraft, its systems and components, and provides oportunity to compare actual reliability data with expected reliability data for the specific aircraft type.
- Expected reliability data are generated:
  - based on previous historical data and experience of the operator and
  - based on global fleet data that are made available by the aircraft manufacturer.

Maintenance Reliability Program

- Continously running the Reliability Program, it is possible todetect negative and positive trends related to the reliability of the aircraft, its systema and components.
- If there is a statistically significant confirmed negative trend in some of the reliability performance indicators, the Reliability Program requires analysis and investigation to take place in order to determine causes of such negative trends.
- Following completed analysis of negative trend, Reliability Program further requires that necessary corrective actions are defined and carried out in order to correct the negative trend.

Fleet size and it’s impact on the quality of statistical reliability data

- → In order to assure that Reliability Program provides statistically reliable data, size of the fleet is of great importance. The bigger the fleet the better the quality of the statistical data.
- → On the small number of the aircraft (1-6), due to the small total number of events that are being monitored by Reliability Program, the collected statistical data tend to scatter and fluctuate between extremes which makes identification of trends more difficult and not so reliable.

Two aircraft fleet

Five aircraft fleet

Two aircraft fleet

TECHNICAL DISPATCH RELIABILITY RATE

CLEAR

MONTH		Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Delays > 15 minutes	No	10	6	2	1	5	10	6	3	3	3	8	0
	r	1,53	0,91	0,30	0,16	0,87	1,96	1,28	0,59	0,77	0,75	1,37	0,00
Cancellations	No	0	0	0	1	1	0	0	0	0	0	0	0
	r	0,00	0,00	0,00	0,16	0,17	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Dispatch Reliability Rate R1		98,47	99,09	99,70	99,68	98,96	98,04	98,72	99,41	99,23	99,25	98,63	100,00
World Fleet Reliability (Last 12 months)*		99,40	99,40	99,40	99,40	99,40	99,40	99,40	99,40	99,40	99,40	99,40	99,40
CTN Goal		99,20	99,20	99,20	99,20	99,20	99,20	99,20	99,10	99,10	99,10	99,10	99,10
ALERT Value		97,70	97,70	97,70	97,70	97,70	97,70	97,70	97,68	97,68	97,68	97,68	97,68

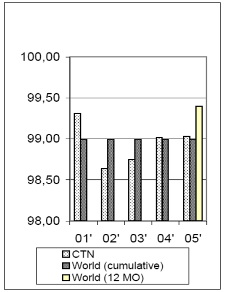
rates per 100 take-offs

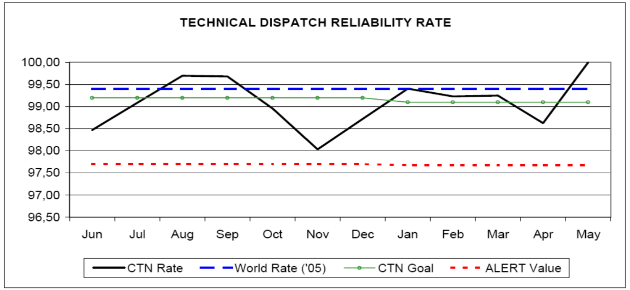
*ATR 42 Operational data 09/2005

LAST 3 MONTHS AVERAGE: 99,29

LAST 6 MONTHS AVERAGE: 99,21

LAST 12 MONTHS AVERAGE: 99,10





CROATIA AIRLINES / TS MONTHLY RELIABILITY REPORT - ATR42 Page: 8

Five aircraft fleet

TECHNICAL DISPATCH RELIABILITY RATE

CLEAR

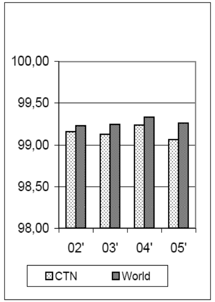
MONTH		Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Delays > 15 minutes	No	26	27	19	18	10	6	5	8	6	5	7	7
	r	1,37	1,35	0,96	0,97	0,61	0,57	0,47	0,76	0,57	0,41	0,56	0,43
Cancellations	No	1	0	0	0	0	0	0	0	0	0	0	0
	r	0,05	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Dispatch Reliability Rate R1		98,57	98,65	99,04	99,03	99,39	99,43	99,53	99,24	99,43	99,59	99,44	99,57
World Fleet Reliability (Sep '05)		99,26	99,26	99,26	99,26	99,26	99,26	99,26	99,26	99,26	99,26	99,26	99,26
CTN Goal		99,20	99,20	99,20	99,20	99,20	99,20	99,20	99,10	99,10	99,10	99,10	99,10
ALERT Value		98,34	98,34	98,34	98,34	98,34	98,34	98,34	98,20	98,20	98,20	98,20	98,20

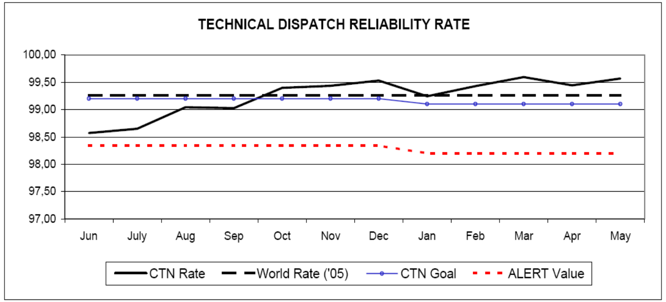
rates per 100 take-offs

LAST 3 MONTHS AVERAGE: 99,53

LAST 6 MONTHS AVERAGE: 99,47

LAST 12 MONTHS AVERAGE: 99,24





CROATIA AIRLINES / TS MONTHLY RELIABILITY REPORT - A320 Family Page: 8

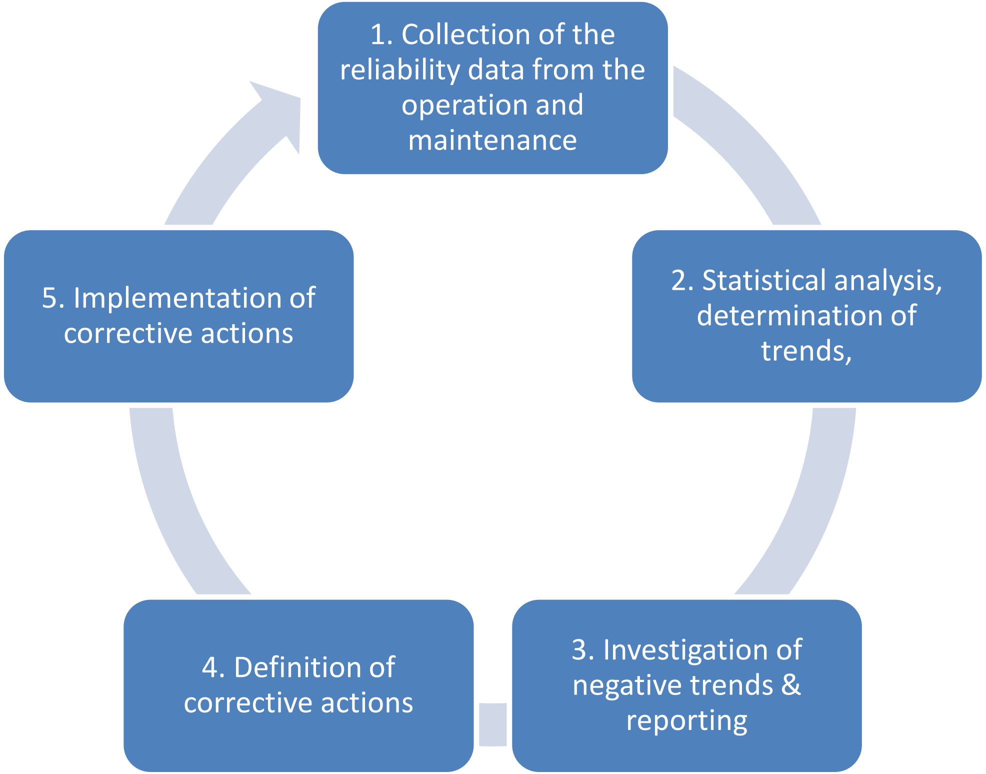
Limitations of the Reliability Program

- By running the Reliability Program, it is not possible to achieve and sustain reliability performance of the aircraft that is above the designed inherent reliability of the aircraft type.
- Reliability of the aircraft, it's systems and components largely depend on the type of the operation, environment and operating/maintenance standards. Therefore, it only makes sense that the Reliability Program is being performed by each operator separately (with possible some exceptions in case of very small fleets)
- Fully functional Reliability Program should produce gradual improvements and optimisation of operator's AMP and should make sure that the aircraft is being maintained and operated in efficient, optimal way to achieve designed relability of the aircraft.

Approval of Reliability Program

- Reliability Program has to be approved by Civil Aviation Authority (normally done through approval of CAME, AMP or separate procedure, depending on where the program has been described.
- While doing analysis of the reliability data and defining ammendments or changes to the AMP it is necessary to apply MSG3 logic if the AMP has been defined based on MSG3.

Basic Flow of the Reliability Program



Responsibilities

- There are different ways how the responsibilities can be distributed within the organization and it largely depends on the size and complexity of the operator's organization. However, industry practice has evolved a typical pattern of responsibility distribution as described bellow.
- Responsibility for overall functioning of Reliability Program is often assigned to the Reliability Control Board.
- Reliability Control Board is a body having management personnel of the engineering and maintenance departments as members.

Responsibilities

- Reliability Control Board manages the whole Reliability Program and makes sure that all elements of the Program are in place and functional and that all activities are carried out in accordance with prescribed procedures within the Reliability Program. It is also responsible to approve corrective actions and monitor that corrective actions have taken place.
- Consequently, Reliability Control Board is responsible to internally approve changes to the AMP.

Reliability Control Board Meetings

- RCB meetings are being held in order to bring on decisions within the Reliability Program. The decisions are being adopted by the means of voting. Normally, depending on the size of the fleet, regular RCB meetings are being held monthly (may be larger interval in case of small organization/fleet).
- Typical questions that are being discussed are:
  - Analysis of current status of the Reliability Program corrective actions implementation
  - Analysis of Reliability Monthly Report, determination of the current situation of the fleet reliability, discussion about the negative (and positive) trends.
  - Decisionmaking about the new corrective actions as a consequence of notified negative reliability trends.
- Every meeting has to be documented by the minutes of meeting, all decisions made shall be entered in the minutes as well as adoption of the monthly relability report.

Participation of CAA

- In line with the oversight responsibilities that CAA have, the should regularly receive Reliability Reports as they are adopted on RCB, as well as the copies of the RCB Meeting Minutes.
- Also, CAA should be informed in advance about the date and time of planned RCB meeting and they should be able to participate in the RCB meetings if they choose so. It is not rare that CAA inspectors participate on the RCB meetings regularly.
- CAA inspectors should have unrestricted access to all relevant information related to the ongoing reliability program.

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Reliability Process Flow

1. step: Collection of data

- Collection of data, its analysis and preparation of reports are normally in the zone of responsibility of the Engineering department.
- However, actual data collection procedure normally involve many other departments like maintenance department, operations, gnd handling, administrative department etc.
- Depending on the size of the fleet, there will be one or more reliability engineers working in Engineering department on the reliability program. All collected data has to end in the hands of these engineers.

1. step: Collection of data

→ Examples of relevant data are:

- → Aircraft operating FH and CY
- → Entries in Aircraft Technical Log Book
- → Information about dealys and cancellations, specifically technical delays and cancellations
- → Information about operational disruptions due to technical reasons
- → Unplanned engine changes
- → Data about technical occurences (*in flight shut down, smoke in cabin* etc.)
- → All component replacements,
- → All continuing technical problems, repetitive failures (Service Difficulty Reports)
- → Work order packages from the scheduled maintenance including non-routine findings and defects raised during the performance of the scheduled maintenance
- → Component repair shop reports

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2. step: Statistical analysis of data

- All collected data has to be verified and sorted,
- Statistical reliability performance indicators have to be calculated.
- Such calculated reliability performance indicators have to be plotted on the charts and entered into tables in order to see the trends.
- Additionally, once a year alert values have to be calculated

Reliability Performance Indicators

- Operator can define as much indicators as he deems necessary. However, standard reliability indicators would be:
  - Number of pilot complaints per 100 landings
  - Number of technical delays (above 15 min) per 1000 flights
  - Number of technical cancellations per 1000 flights
  - Number of component unscheduled replacements per 1000 component FH
  - Number of engine in flight shut downs per 1000 EFH
  - Number of unplanned engine removals per 1000 EFH
  - Number of repeating pilot complaints
  - Percentage of the dispatches with one, two, three and more open MEL items
  - Long lasting and repeating failures (Service difficulty reports)
  - Defects raised during the scheduled maintenance

Upper/lower Control Limits or Alert Values

- For each of monitored performance indicators, there should be alert value defined.
- Purpose of the Alert value is to delineate border between statistically acceptable performance and statisticaly unacceptable or deviant performance.
- Every time the actual performance parameter has crossed the Alert value, that means that it is a substantial and statistically significand deviation from expected normal values.

Alert Status

- In relation to the Alert Values, in Monthly Reliability Reports, each performance indicator gets assigned with appropriate „alert status”. Purpose of this is to make the report easier and faster to read for RCB members and other. Usually there are following alert statuses:
  - CLEAR - normal status, current month and running last three months average, the observed performance indicator is bellow alert value;
  - YELLOW – is indicated when alert value has been exceeded for two consecutive months, which means that there is a high likelihood that there is some negative development, which will be confirmed if the exceedance of alert value continues into the third month.

Alert Status

- RED – this status is assigned to the confirmed negative trend, meaning that the alert value has been exceeded for three consecutive months
- REMAINS IN ALERT – is assigned to the performance indicator in case exceedance of alert value continues in the fourth and further months (no improvement)
- WATCH – is assigned to the performance indicators that are showing improvement after being in red status, also to the performance indicators which should be more closely monitored for some reason.

Determination of Alert Value

- Aleert values are calculated using standard deviation formula. Last 12 months of reliability data are used in the statistical calculation of alert values. This calculation is normally done once a year.
- Mostly depending on the size of the fleet and corresponding data scatter, it is important to define alert values not to be too low (too sensitive) because that would trigger nehgative trends too often, but also not to be set too high so that no exceedances really can be recorded.
- In order to adjust sensitivity of the alert value, we use mean value of the performance indicator with added 2σ (for the small scatter of data = big fleets) up to 3σ (for the larger scatter of data = small fleet).

Determination of Alert Value

a) Calculation of standard N-1 deviation:

$$\sigma = \sqrt{\frac{\Sigma(x^2) - \frac{(\Sigma x)^2}{N}}{N - 1}}$$

Where:

- x = monthly value of the given reliability performance indicator
- Σ = sum
- N = number of months that are taken into calculation

Determination of Alert Value

b) Calculation of Alert Value (in this case -*Upper Control Limit* -UCL):

$$UCL = \overline{x} + k\sigma$$

Where:

→ = Σx / N

→ k = standard deviation multiplying factor (between 2 and 3)

This calculation should be repeated every 12 months.

Excercise – calculation of Alert Value

Number of month	Month - Year	X	X^2
1	Jul - 90	3.08	9.49
2	Aug - 90	3.55	12.60
3	Sep - 90	4.09	16.73
4	Oct - 90	3.28	10.76
5	Nov - 90	3.70	13.69
6	Dec - 90	3.86	14.90
7	Jan - 91	3.28	10.76
8	Feb - 91	3.54	12.53
9	Mar - 91	3.44	11.83
10	Apr - 91	3.89	15.13
11	May - 91	3.70	13.69
12	Jun - 91	3.15	9.92
N=12	Sum:	ΣX=42,56	ΣX^2=152,03

Analysis and Presentation of Reliability Data

- In order to facilitate assessment and decision making regarding the fleet reliability, it is required to prepare a monthly Fleet Reliability Report in which the relability data will be presented in detail in systematic manner and concise form (tables, diagrams)
- These reports should clearly indicate and identify all negative trends of the monitored reliability indicators.

Analysis and Presentation of Reliability Data

- Monthly fleet reliability reports are published for each aircraft type separately and serves as a basis for further investigation and analysis as well as a basis for decisionmaking of the RCB.
- Monthly Reliability Report is normally being produced by reliability engineer – engineering department.

Contents of Monthly Reliability Report

- Usually divided in two parts:
- Introductory part containing summary reliability data with all important information (alert items, technical incidents) and general data about the operation (FH, number of flights...)
- Detailed report about:
  - The operation of the fleet
  - Report for each reliability performance indicator:
    - Number of pilot complaints per 100 landings
    - Number of technical delays (above 15 min) per 1000 flights
    - Number of technical cancellations per 1000 flights
    - Number of component unscheduled replacements per 1000 component FH
    - Number of engine in flight shut downs per 1000 EFH
    - Number of unplanned engine removals per 1000 EFH
    - Number of repeating pilot complaints
    - Percentage of the dispatches with one, two, three and more open MEL items
    - Long lasting and repeating failures (Service difficulty reports)
    - Defects raised during the scheduled maintenance

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Analysis of statistical data

- Whenever some indicator exceeds the alert, relability engineer will perform the analysis to verify the data and determine the cause of such exceedance.
- Results of such analysis are presented in the report and on the RCB meeting. The analysis should provide detailed insight in all events that contributed to the exceedance and should find the causes. In case exceedance continues in the next two months, based on all analysis performed, reliability engineer shall propose potential corrective actions to the RCB.

Analysis of statistical data

→ Main causes of negative trends may be:

- → Inadequate preventive maintenance, defficiency in the Maintenance Program,
- → Lack of certain knowledge in engineerin, maintenance or operation,
- → Not sufficiently specified maintenance procedures,
- → Not following defined maintenance procedures,
- → Unserviceable tooling or ground service equipement,
- → Significant changes in the operation of the aircraft (new destinations, area of operation, seasonality, changes in climate...),
- → Pilots procedures being not adhered to,
- → Operation in the environment outside of certification limits

Corrective action

→ After the analysis of the causes of exceedances have been performed, root causes of the negative trend is being determined and reliability engineer or engineering department recommends corrective action or actions that should remedy the problem.

Corrective action

- Corrective actions are being discussed and adopted on RCB meeting and they may be:
  - Change of the Maintenance Program (introduction of new tasks, shortening of task intervals, changes in the scheduled tasks)
  - Additional inspection campaign on the fleet to determine status of some problematic system fleetwise
  - Performance of the modification (usually SB) that prevents certain problems
  - Changes in the operational procedures
  - Training of personnel (maintenance, engineering, ground handling, flight ops...)

Corrective action implementation monitoring

- At the adoption of the corrective action on the RCB meeting, manager responsible for carrying out the corrective action is being named as well as responsible departments.
- Each corrective action is given a deadline and responsible manager is taking care that the corrective action is carried out as defined within the given time. While corrective action is being implemented, responsible manager is reportin about the status of implementation on the RCB meeting.

Corrective action implementation monitoring

- RCB will address each ongoing corrective action on its regular meetings, monitor the progress and apply pressure if necessary to enforce implementation of the corrective action.
- Efectivity of implemented corrective action is measured by the reliability program process itself. Efficient corrective action should result in reversed negative trend and improvement of reliability

End of presentation

Thank you for your attention!

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SAFA – Safety Assessment of Foreign Aircraft

Omer Pita and Salvador Alepuz
Airworthiness Experts

Your safety is our mission.

An Agency of the European Union

Introduction

- SAFA is result of the growing concern that ICAO standards are not applied at the adequate level in all ICAO member states
- European initiative by European Civil Aviation Conference - ECAC
- Initial discussions 1994/1995
- June 1996: adoption of SAFA programme by ECAC DGCA meeting
- The SAFA program involves performance of the ramp inspections on foreign aircraft

ICAO regulatory provision used for third country aircraft ramp inspections

Article 16

Search of aircraft

The appropriate authorities of each of the contracting States shall have the right, without unreasonable delay, to search aircraft of the other contracting States on landing or departure, and to inspect the certificates and other documents prescribed by this Convention.

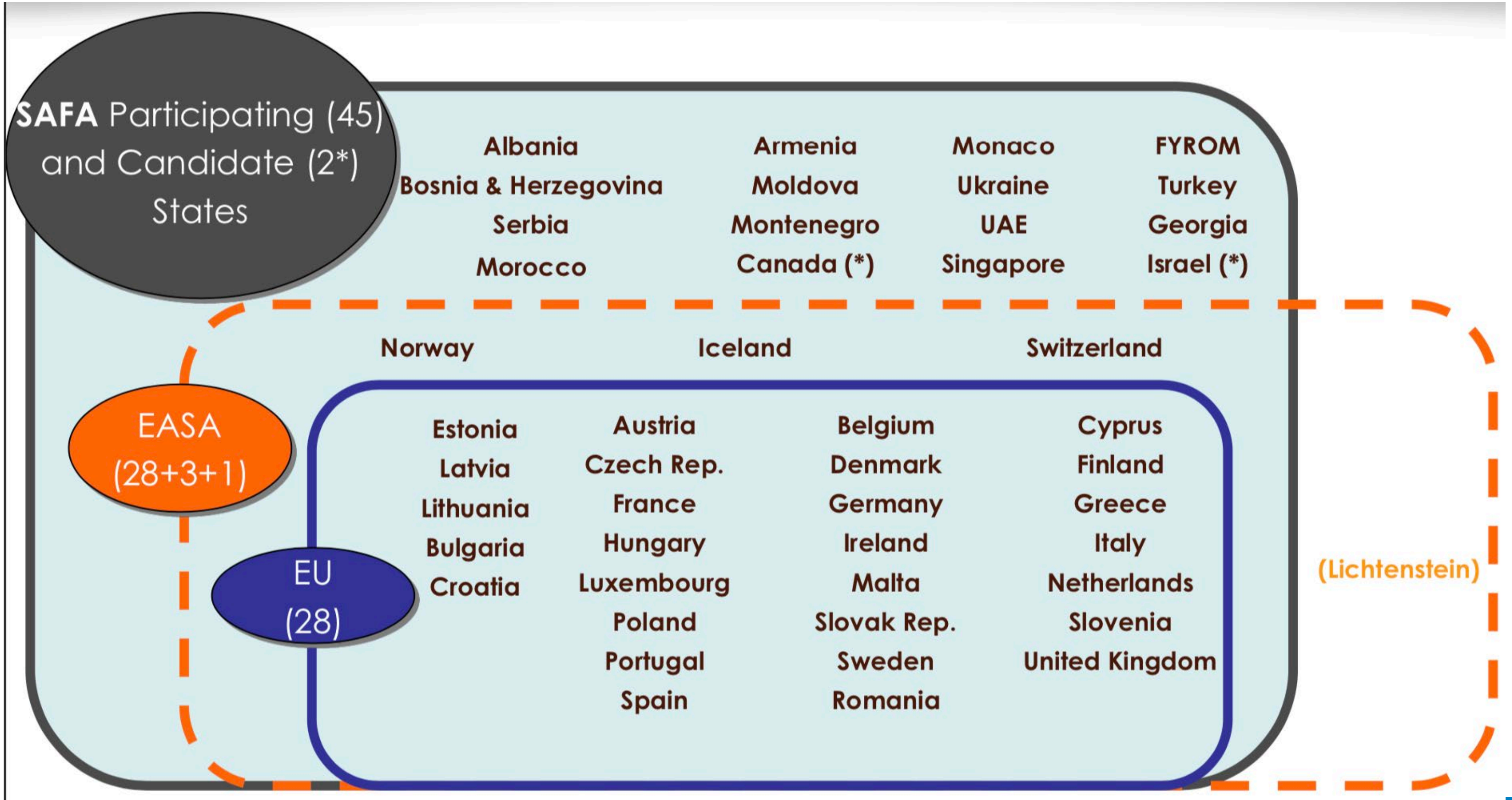
SAFA Programme

- → Voluntary basis until April 2006
- → SAFA Directive (2004/36/CE) to be implemented by EU Member States by 30/04/2006
  - → Introducing legal obligation upon EU MS:
  - → to inspect third-country aircraft landing at their airports
  - → to participate to the collection and exchange of information on the ramp inspections carried out
  - → possibility to inspect aircraft from other EU MS
  - → Not applicable to State aircraft
- → As of 01/01/2007 SAFA transferred to EC and EASA by means of Commission Regulation No 768/2006

SAFA Programme

- Based on compliance with ICAO (regional) standards, manufacturer's standards and compliance with EU airspace operating criteria, such as RVSM, BRNAV, RNP requirements
- Considered as complementary to ICAO USOA Programme
- Bottom-up approach
- A single set of procedures for the performance of the ramp inspections
- A single tool => centralised SAFA Database
- A single syllabus for training and qualification of inspectors
- Standardisation – ensuring long term data quality improvements
- Risk based prioritisation: a tool to make SAFA more effective

SAFA Participating States



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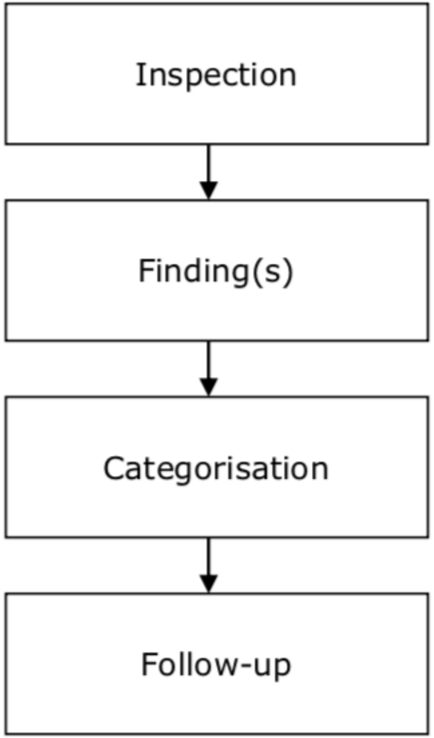
SAFA Process



Who should be aware of SAFA inspections

- → Flight deck crew
- → Cabin Crew
- → Maintenance provider
- → Dispatchers
- → Cargo Handlers
- → Station Managers and Staff
- → NAA of Operator
- → Operator Quality system staff

SAFA Ramp Inspections cover all activities visible on Ramp

- Flight Planning
- Flight crew management
- Licenses
- Aircraft documentation
- Loading
- Dangerous goods
- Maintenance
- De-Icing
- Cabin safety and security preparation
- Dispatch
- Aircraft external condition

SAFA Check list inspection items

- → The report form lists 54 inspection items.
- → Due to the limited availability of the aircraft being inspected not all items and audited at any one visit. Priority is given to the ‘critical’ items. The rest may be completed over several audits.
- → Inspectors are trained under supervision of EASA.
- → The check list used the SAFA inspection team is published on the EASA website
- → Inspection procedures are NOT published

SAFA Findings

- Non-compliance with ICAO Annexes or manufacturer's standards or EU airspace standards
- Ramp Inspection procedure contains 600 pre-described findings
- If no suitable pre-described finding is available, the inspector may create its own user described finding

Pre-described Findings

- Advantages:
- Harmonisation and Standardisation
- Common & clear descriptions
- Standardised categorisation i.a.w. (ICAO) standard
- Minimised number of ambigous findings

Defficiencies that are accounted for by the Operator

GM2 ARO.RAMP.125(a) Conduct of ramp inspections

DEFICIENCIES UNDER THE CONTROL OF THE OPERATOR

Deficiencies under the control of operators in accordance with applicable requirements are not to be considered as non-compliance: e.g. if an aircraft diverted because of a technical defect is inspected upon arrival, such defect should not be considered as a non-compliance and no finding should be raised, as long as the defect is properly reported (e.g. through the Technical Log Book) and subsequently assessed.

Follow up actions

- Class 1
  - Information to the PIC - Proof of inspection
- Class 2
  - Class 1 actions, and in addition:
  - Written communication to operator (request for corrective actions)
  - Written communication to the Authority (informative, possibly asking for involvement)

Follow up actions

- Class 3
  - Class 1 and 2 actions, and in addition:
  - Aircraft may only depart after:
    - Restrictions have been imposed
    - Corrective actions have been taken
- If no appropriate actions are taken:
  - Aircraft may be grounded
  - Full or partial ban may be imposed

Planning of SAFA inspections

- All SAFA findings are entered in SAFA Database
- Findings in the SAFA Database are being regularly analysed and based on the data analysis SAFA Ratio is being determined for each operator and state
- SAFA Ratio is (SAFA/Safety) Performance Index
- Every 4 months the analysis is being performed after a quality review of the findings
- Output: Operators list sorted on ratio Approximate 600+ operators

SAFA In depth Analysis

- Manual analysis by EASA and 6 experts from EU Member States
- Considered operators determined by: previous analysis, or a SAFA ratio of more than 2 and having more than 6 inspections (sometimes with exceptions)
- Levels of advice to member states and/or Commission:
  - (1) Safety concern – triggers Focused Inspections
    (2) Significant concern – triggers EASA letter to request corrective actions
  - (3) Major safety concern - EASA TCO escalation/ Commission investigations under 2111/2005
  - (0) Sustained improvement - stop Focused inspections

Prioritisation of inspections

- EASA maintains a list of operators/aircraft identified as presenting a potential risk for the prioritisation of ramp inspections
- List based on (amongst other aspects):
  - EASA SAFA/SACA analysis (SAFA Ratio)
  - EU Air Safety list
    - Air Safety Committee opinions
    - operational restrictions (Annex B)/Certified by States with other operators on SL
  - TCO that operates in the EU for the first time or whose TCO authorisation is limited or reinstated after suspension or revocation

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Prioritisation of inspections

- EASA priority list and subsequent intensified inspections are being monitored by Monitoring tool in SAFA database
- Increased number of inspections should confirm either: safety deficiencies or normal or improved safety performance

Obligation of EU Member States

- Requires EU States to carry out an agreed number of minimum inspections – more may be required as necessary
- There is a calculation formula which defines the amount of the contribution of each member state to the total number of the SAFA inspections

SAFA is Integrated with other safety processes in EU

- Systemic risks are addressed on multiple levels:
  - EASA: the Standardisation of EASA states
  - EASA/COM: requests to competent NAAs
  - EC: opening investigations under the Safety List
  - EASA TCO
- SAFA Ratio is Indicator for risk based data driven processes:
  - Continuous Monitoring Approach (CMA) for EASA standardisation
  - Oversight of TCO
- Regulatory feedback

Impact of poor operator's response to SAFA

- Poor management of handling of SAFA findings by Operators and their respective States are the most common cause of the commencement of banning sanctions
- SAFA findings must be tracked, rectified and properly closed in timely manner followed by communication with EASA
- Operators and States should put in place SAFA Response Procedures which will expeditiously and clearly deal with SAFA findings

Right of Defence for Blacklisted Carriers

- Regulation 473/2006 (Implementing Rules) gives more detail on the Right of Defence of a **restricted** carrier:
  - Carrier given 10 days in which to advise EC of defence
  - EC consults member States of the ASC
  - Carrier defence submitted to interested States at hearing convened by the EC
  - Right of defence does not preclude EU member State to restrict operations of carrier
  - EC must advise operator and its Regulatory Authority of the EC decision.

SAFA Centralized Database

- Web based application for exchange of information
- Storage of Ramp Inspection Reports
- Access for each Participating State
  - entering of the reports
  - retrieve data
- Access for guest States and for operator
  - inclusion of follow-up informatio
  - retrieve data
- Stored information is confidential EASA does not own the data!

SAFA Centralized Database

- Access granted to Guest NAAs and to operators:
- registered Guest NAAs have access limited to the reports of the operators for which they have regulatory oversight responsibilities
- operators' access is limited to their own reports
- Guest NAAs and operators are able to retrieve their relevant reports and add information on follow-up actions taken
- TCOs access can be obtained via the relevant Guest NAA in 2 steps:
  - the Guest NAA will give a first approval to the operator user
  - SAFA administrator will approve the access

SAFA in detail

→ Link to SAFA Ramp Inspections Guidance Material

End of presentation

Thank you for your attention!

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Safety Management System and Mandatory Occurence Reporting

Omer Pita and Salvador Alepuz
Airworthiness Experts

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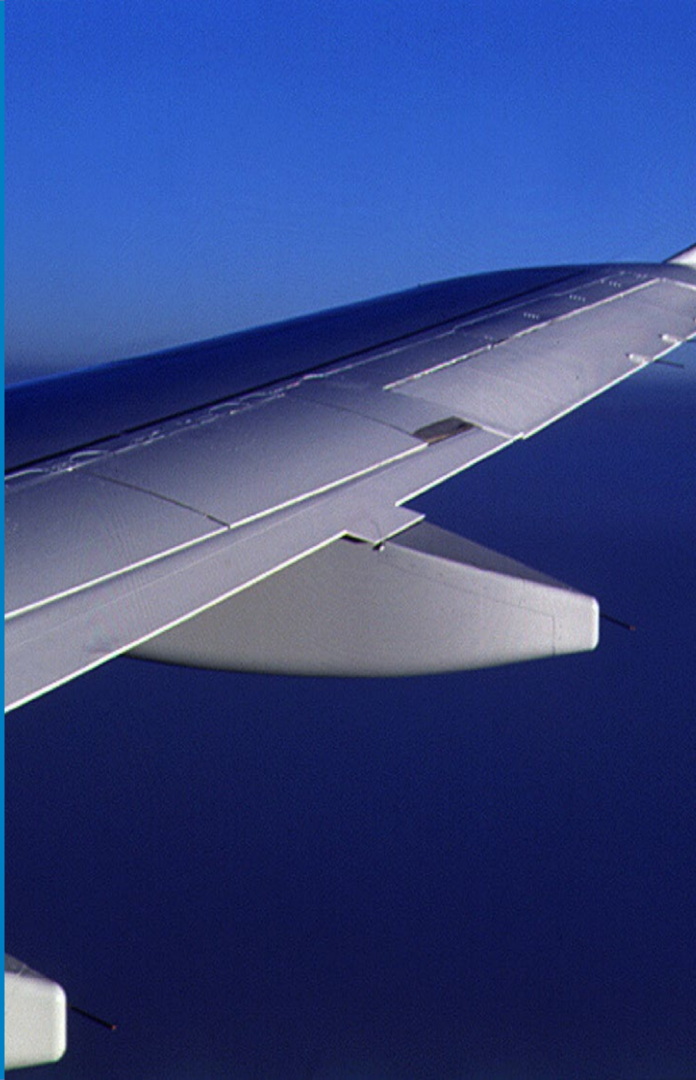
Safety Management Systems



ICAO DOC 9859 Definition od Safety

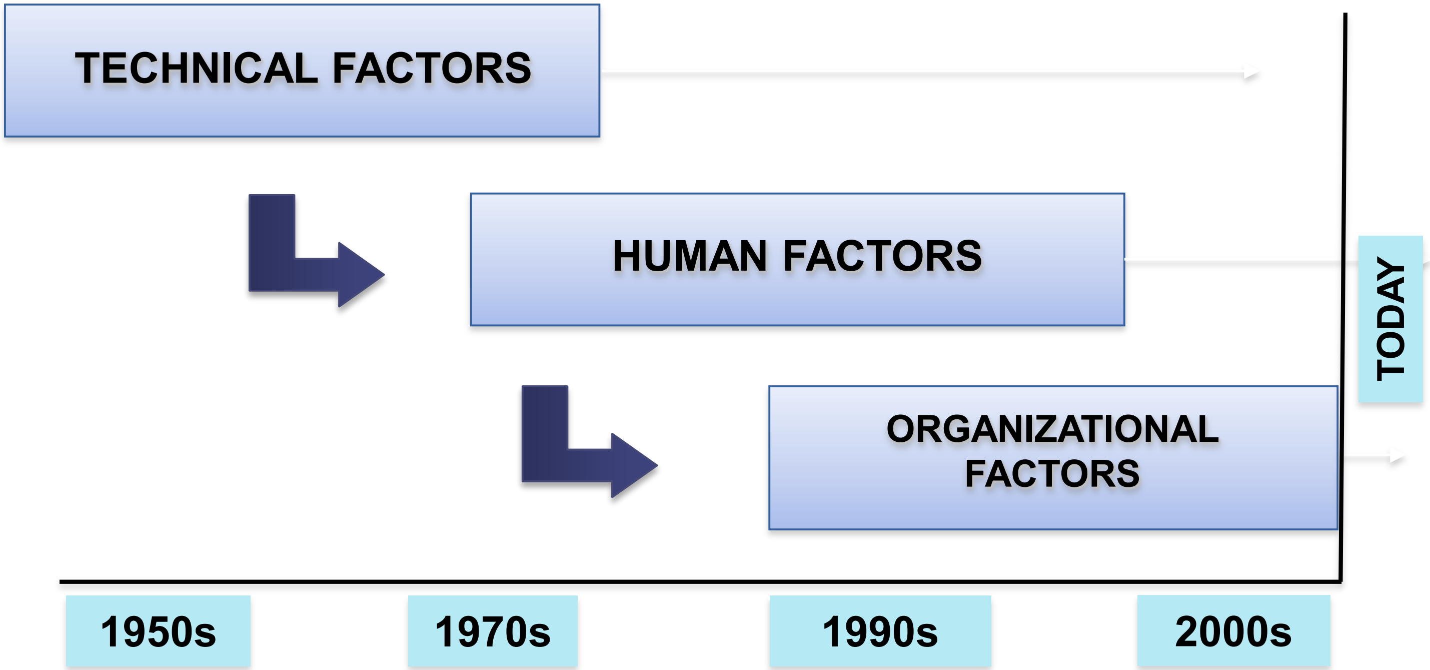
Within the context of aviation, safety is

→ the state in which the possibility of harm to persons or of property damage is reduced to, and maintained at or below, an acceptable level through a continuing process of hazard identification and safety risk management.‖

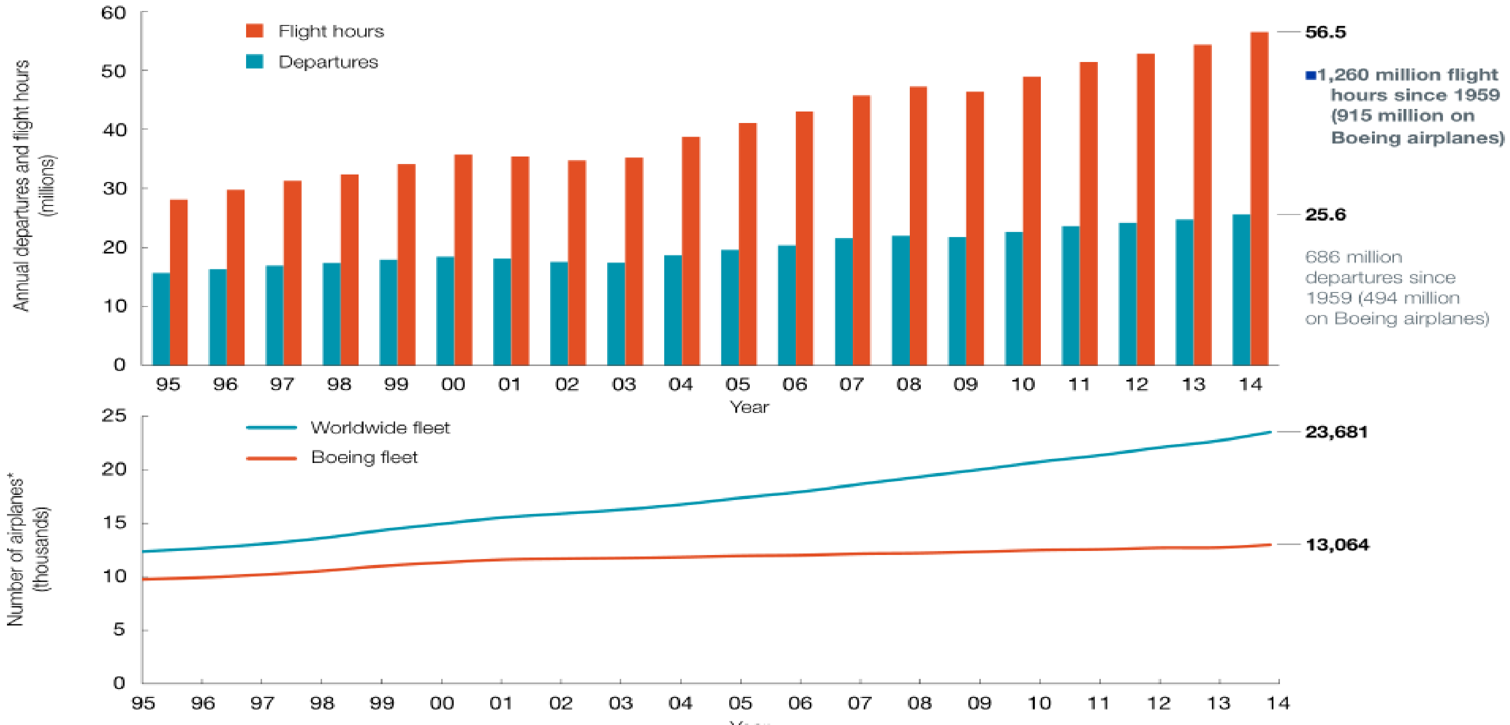
Concepts of Safety Throughout the History

- Technical Era : from 1900 till 1970
  - focus was on technical factors
- Human Factors Era: from 1970 till 1990
  - focus was on human factors
- Organizational Era : from 1990 till Today
  - focus is on on technical , human factors and organizational factors

The Evolution of Safety Thinking



Growth of world fleet operation



Source: Jet Information Services, Inc.

* Certified jet airplanes greater than 60,000 pounds maximum gross weight, including those in temporary non-flying status and those in use by non-airline operators. Excluded are commercial airplanes operated in military service and CIS/USSR-manufactured airplanes.

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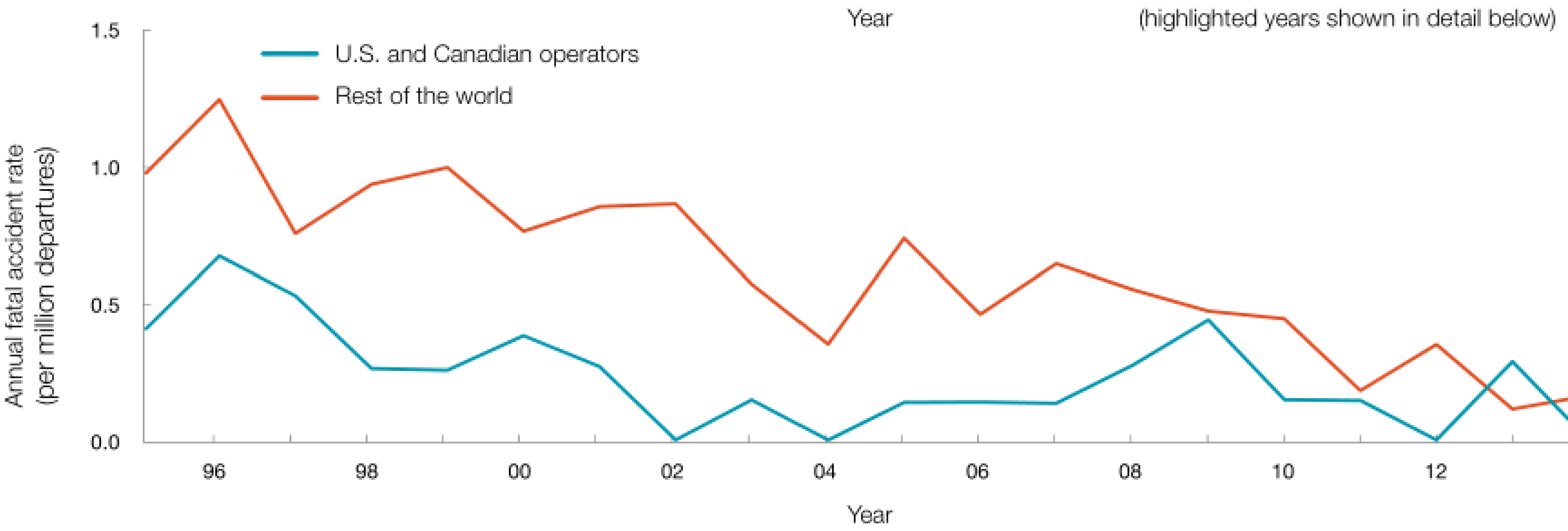
Safety record for the same period



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How do we make errors?

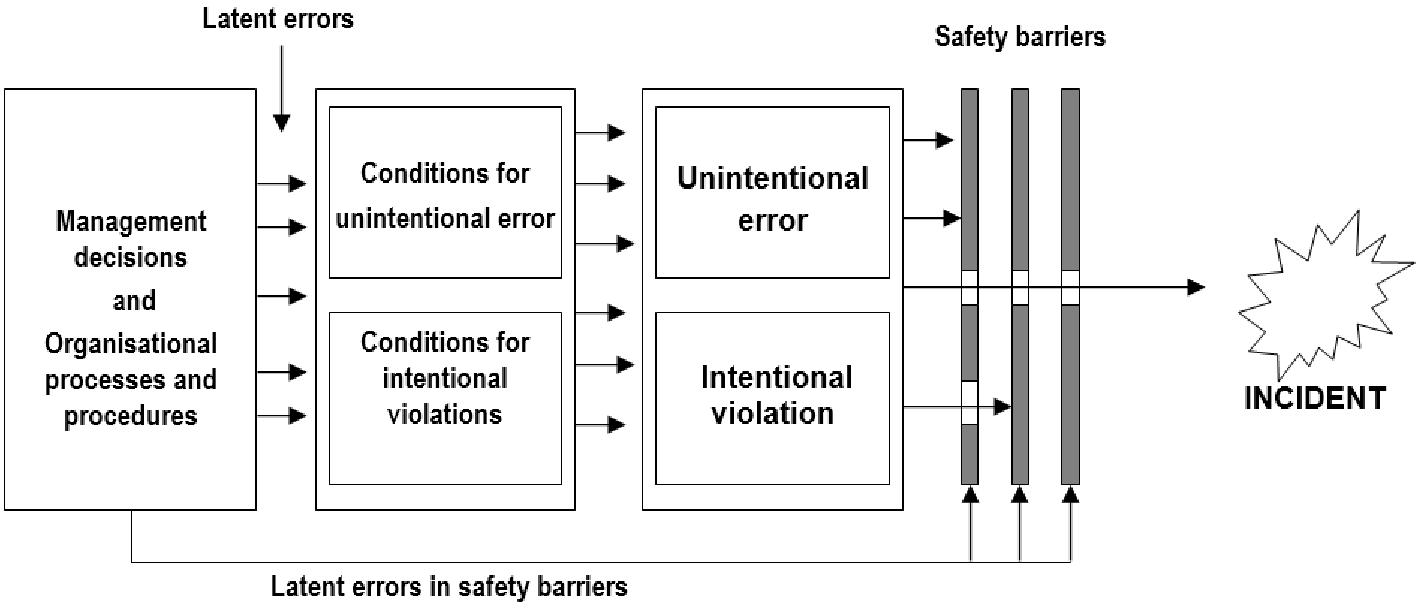
Traditional Approach to safety

- In the past Aviation Safety Investigations concentrated on:
  - What happened
  - When did it happen
  - Who to BLAME
- The problem is that all aircraft accidents/incidents involve many subtle details that contributed to the event that are being overlooked while trying to find the person to blame
- Such approach generated so called ”Blame Culture”, everyone is afraid to speak out about issues, mistakes and errors.
- Large quantity of safety related data is being not accessible

Modern Approach to Safety

- Aviation Safety Investigations today look for answers:
  - How did it happen?
  - Why did it happen?
  - What was the root cause and what were contributing factors?
  - How to prevent reccurence of incident/accident?
- All humans are prone to make errors, question is what caused them to make the error?
- Errors are not occuring only and exlusively at the level of the operating personnel (pilots, engineers, gnd. handlers...)
- They are occuring throughout the organisation levels including the management levels

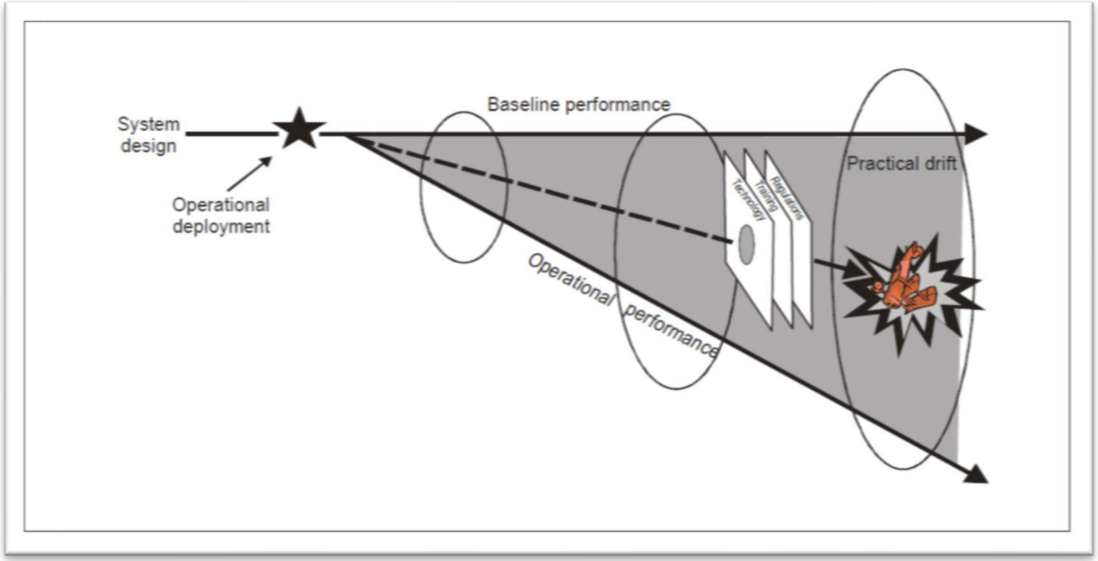
James Reason concept of Organisational Accident



Development of organisational error – source James Reason

The practical drift

→ Scott A. Snook's theory of practical drift is used as the basis to understand how, in aviation, the baseline performance of any system „drifts away” from its original design when the organization’s processes and procedures cannot anticipate all situations that may arise in daily operations.



Errors and Violations

- An error is defined as - an action or inaction by an operational person that leads to deviations from organizational or the operational person's intentions or expectations.
- A violation is defined as - a deliberate act of wilful misconduct or omission resulting in a deviation from established regulations, procedures, norms or practices.
- while violations are intentional acts, they are not always acts of malicious intent.

Types of Errors

- **Slips and lapses** are failures in the execution of the intended action. Slips are actions that do not go as planned, while lapses are memory failures. For example, operating the flap lever instead of the (intended) gear lever is a slip. Forgetting a checklist item is a lapse.
- **Mistakes** are failures in the plan of action. Even if execution of the plan were correct, it would not have been possible to achieve the intended outcome.

Error fighting strategies

- **Reduction strategies** provide direct intervention to reduce or eliminate the factors contributing to the error. Examples of reduction strategies include improvement of ergonomic factors and reduction of environmental distractions.
- **Capturing strategies** assume the error will be made. The intent is to capture the error before any adverse consequences of the error are felt. Example of capturing strategies in aircraft maintenance are duplicate inspections (RII).
- **Tolerance strategies** refer to the ability of a system to accept that an error will be made but without experiencing serious consequences. The incorporation of redundant systems does increase tolerance of the system to the human errors.

Types of violations

- **Situational violations** are committed in response to factors experienced in a specific context, such as time pressure or high workload.
- **Routine violations** become the normal way of doing business within a work group. Such violations are committed in response to situations in which compliance with established procedures makes task completion difficult. These deviations, referred to as „drift", may continue without consequence, but over time they may result in potentially severe consequences.
- **Organizationally induced violations** may be considered as an extension of routine violations. This type of violation tends to occur when an organization attempts to meet increased output demands by ignoring or stretching its safety defences.

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Culture and Reporting

Culture

- **National culture** encompasses the value system of particular nations
- **Organizational/corporate culture** differentiates the values and behaviours of particular organizations (e.g. government vs. private organizations)
- **Professional culture** differentiates the values and behaviours of particular professional groups (e.g. pilots, air traffic controllers, maintenance engineers, aerodrome staff, etc.)
- No human endeavour is culture-free

Safety Culture

- A **safety culture** encompasses the commonly held perceptions and beliefs of an organization's members pertaining to the public's safety and can be a determinant of the behaviour of the members.
- A healthy safety culture relies on a high degree of trust and respect between personnel and management and must therefore be created and supported at the senior management level.
- **Organizational culture** refers to the characteristics and safety perceptions among members interacting within a particular entity. Organizational value systems include prioritization or balancing policies covering areas such as productivity versus quality, safety versus efficiency, financial versus technical, professional versus academic, and enforcement versus corrective action.

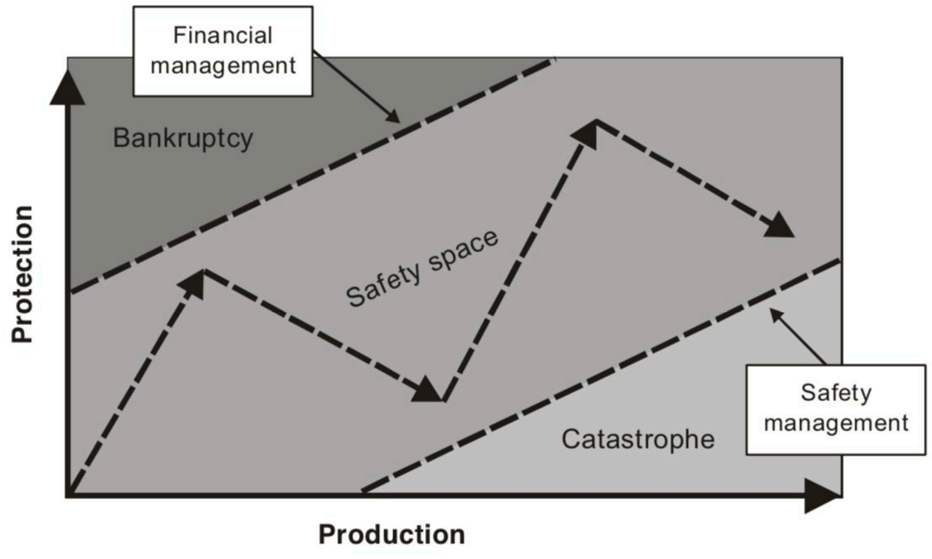
Reporting Culture

- **Reporting culture** emerges from personnel beliefs about and attitudes toward the benefits and potential detriments associated with reporting systems and the ultimate effect on their acceptance or utilization of such systems.
- It is <u>greatly influenced by organizational, professional and national cultures</u> and is one criterion for judging the effectiveness of a safety system.
- A healthy reporting culture aims to differentiate between intentional and unintentional deviations and determine the best course of action for both the organization as a whole and the individuals directly involved.

Management Aspects Related to the SMS

The Management Dilema

- In any organization engaged in the delivery of services, production and safety risks are linked.
- As production increases, the safety risks may also increase if the necessary resources or process enhancements are not available.



Source: James Reason

Change Management

- Aviation organizations, including regulatory authorities, experience change due to expansion and contraction as well as changes to existing systems, equipment, policies, programmes, services and regulations.
- Hazards may inadvertently be introduced into the aviation system whenever change occurs. Existing baseline safety risk mitigation processes may also be impacted.
- Safety management practices require that hazards resulting from change be systematically identified, and strategies to manage the consequential safety risks be developed, implemented and subsequently evaluated.

Integration of Management Systems

- Typical management systems within an aviation organization may include:
  - a) a quality management system (QMS);
  - b) a safety management system (SMS);
  - c) a security management system (SeMS);
- A holistic organizational management system has often been referred to as an integrated management system or simply the organizational - management system.

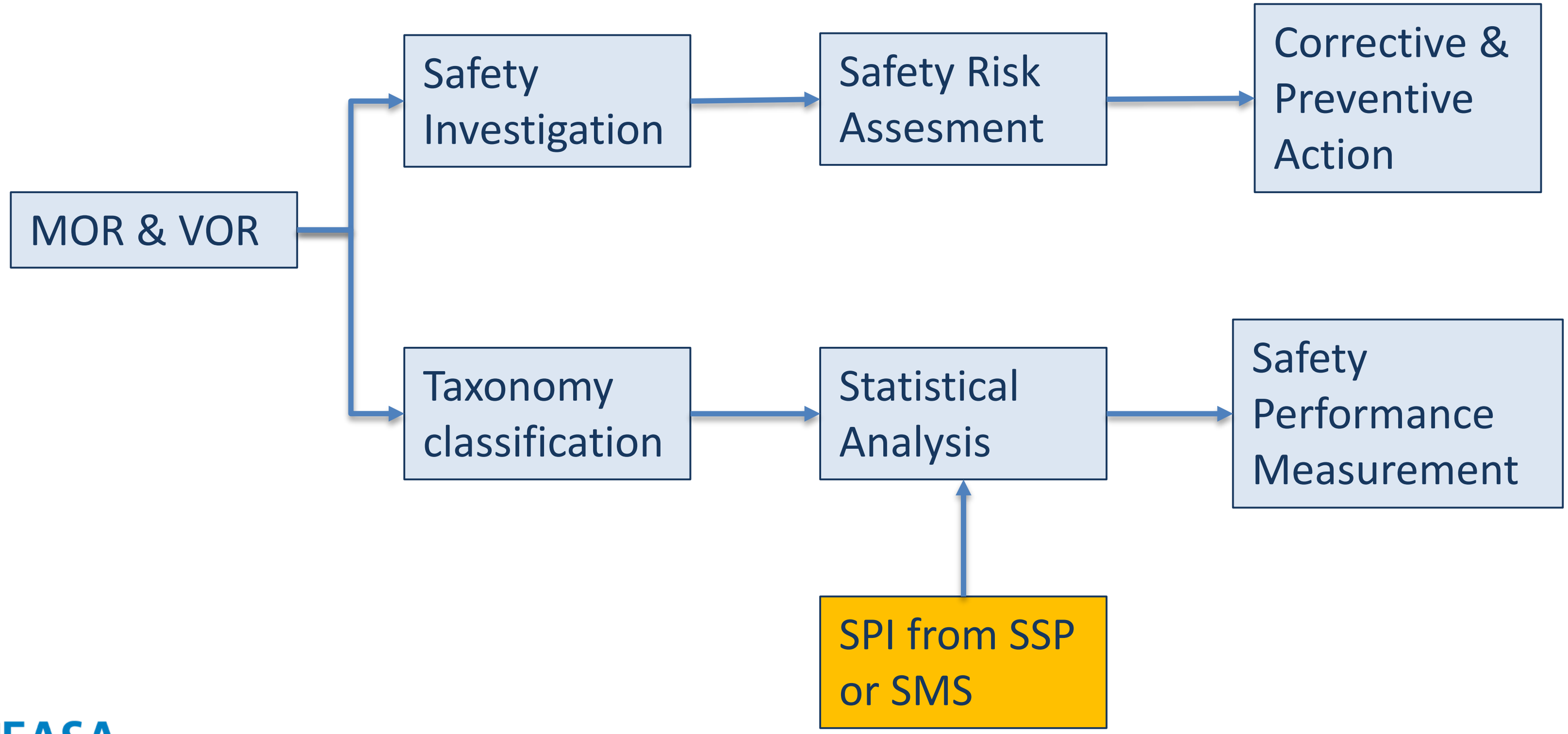
Relationship Between Safety and Quality

Safety Reporting Schemes

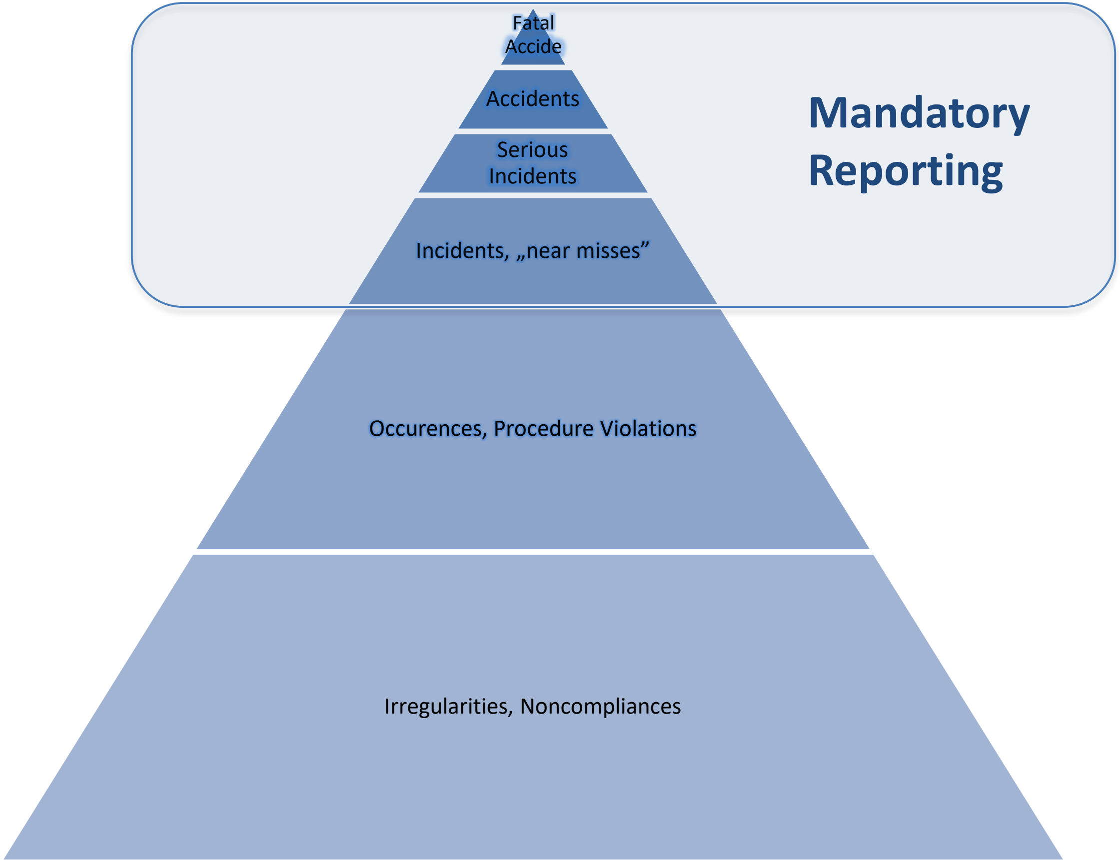
Safety Reporting

- Accurate and timely reporting of relevant information related to hazards, incidents or accidents is a **fundamental activity of safety management.**
- The data used to support safety analyses are reported by multiple sources.
- One of the best sources of data is direct reporting by front-line personnel since they observe hazards as part of their daily activities.

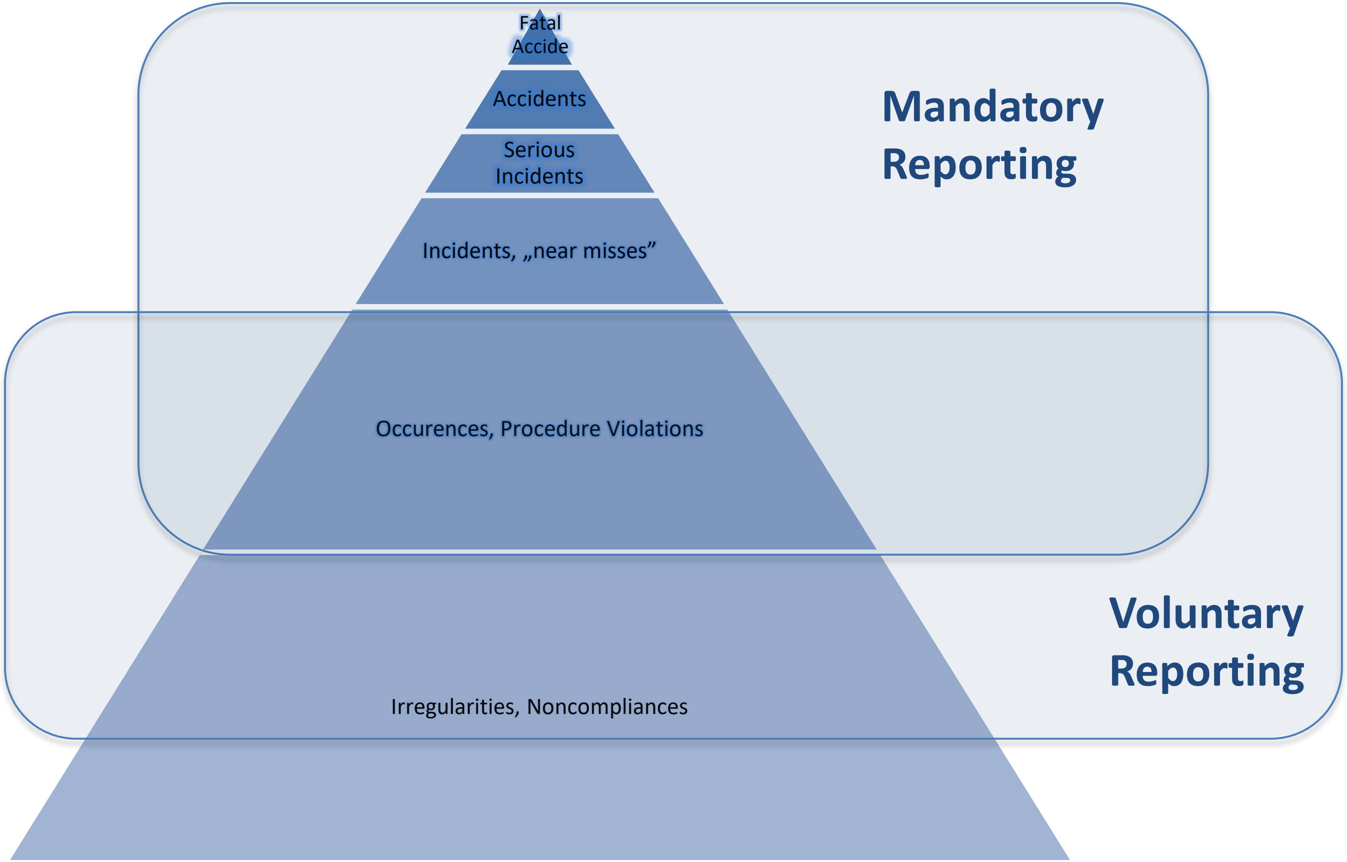
Safety Reporting is the very Foundation of the SMS



Traditional Ocurrence Reporting Scheme



Modern Ocurrence Reporting Scheme



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EU Directive 2003/42/EC

- ‘occurrence’ means an operational interruption, defect, fault or other irregular circumstance that has or may have influenced flight safety and that has not resulted in an accident or serious incident, hereinafter referred to as ‘accident or serious incident’...
- it introduces mandatory reporting of occurences and suggests to the member states to additionally establish voluntary reporting system
- the list of mandatory reportable occurences is extensive!
- link to EC 2003/42

ICAO DOC 9859 about occurence reporting

- → While regulatory requirements for mandatory reporting of high-consequence occurrences (accidents, serious incidents) are common, a mature safety management environment will provide for the reporting of lower-consequence events as well.
- → This will allow for the necessary monitoring mechanisms to address all potential high-consequence outcomes.
- → The trend (rate of occurrence) of lower-consequence events is inevitably a precursor of higher-consequence outcomes to come.

Mandatory Reporting

- Pursuant to [Regulation reference(s)], it is mandatory for [Named stakeholders] to report aviation accidents, serious incidents, incidents and other safety related occurrences (including defects/malfunctions/service difficulties) to [Authority/agency name and department].
- 1.2 The list of reportable occurrences (apart from accidents) and the reporting timelines should be provided in this procedure. [Remark: States are encouraged to include low level occurrences deemed reportable under this mandatory reporting system.]
- 1.3 The reporting of mandatory occurrences is done using the Mandatory Report [Form XYZ]. All Mandatory Reports are signed by the approved/certificated organization’s authorized signatory where applicable.

Processing of Mandatory Reports

- The report will then be classified into the following categories:
- a) accident;
- b) serious incident;
- c) incident;
- d) occurrence.

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Processing of Mandatory Reports

- After classification, the report record will be uploaded into the appropriate database with an assigned occurrence reference number.
- 2.4 The status of each report will be categorized and updated as follows:
- a) Initial notification: For evaluation/follow-up/information as annotated.
- b) Under investigation: Investigation by [Accident investigation authority/CAA/service provider] in progress as annotated.
- c) Investigation completed: Investigation results/data received and uploaded.
- d) Closed: No further action required.

Clasification of Occurences

- The classification of accident, serious incident and other incident will be based on ICAO Annex 13 definitions.
- Occurrences that are classified as accidents or serious incidents may require independent investigations by the accident investigation authority. In such cases, the assigned CAA representative tracks the independent investigation process outcomes and provides updates to [Name of CAA database] as necessary.
- For incidents and other occurrences (including defects/malfunctions/service difficulties) that are not the subject of the State's independent investigation process, the assigned CAA representative will liaise with the relevant party for necessary follow-up investigation and report submission as applicable.

Follow-up/Investigation

- For occurrences that require follow-up action or investigation by the service provider’s internal safety/quality function, the relevant CAA representative will liaise with the service provider’s authorized safety/quality representative to ensure the timely follow-up and closure of the occurrence as appropriate.
- The assigned CAA representative monitors and determines whether CAA intervention before, during or after a service provider’s internal safety occurrence investigation and resolution process is necessary.

Follow-up/Investigation

- CAA representative enters all follow-up information received into the relevant database. In the case of investigation reports issued by accident investigation authority, the CAA representative liaises with that authority for the necessary uploading of such data reports into the database.
- Where CAA administrative (enforcement) action following the conclusion of an occurrence investigation report is deemed necessary, such recommendations are forwarded by the relevant inspector to the DGCA for approval in accordance with CAA enforcement procedure Reference xxx.
- In the case of investigation reports issued by [Name of accident investigation authority] due consideration must be given to the objective of the investigation set forth in Annex 13.

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Safety Performance Indicators

Types of SPI (ICAO DOC 9859)

- High-consequence indicators
  - related to accidents, serious incidents
- Lower-consequence indicators
  - related to noncompliances, incidents and occurences

Types of SPI (EASA)

- Tier 1 Safety Performance Indicators
  - Accidents, as defined by ICAO Annex 13, by state of operator.
  - Normalisation of data is calculated as a rate per (million) flights.
- Tier 1 SPIs have been agreed by the group as follows:
  - SPI 1: Commercial Air Transport Large Aeroplanes
  - SPI 2: Commercial Large Helicopters
  - SPI 3: Commercial Light Helicopters
  - SPI 4: Other Commercial Fixed Wing
  - SPI 5: Private Flying

Types of SPI (EASA)

- Tier 2 Safety Performance Indicators
- Tier 2 SPIs are based on occurrence types instead of operation types.
- The scope of the tier 2 indicators is as follows:
  - Accidents, serious incidents, incidents, as defined by ICAO Annex 13, by state of operator.

Types of SPI (EASA)

→ Tier 2 Safety Performance Indicators (2014)

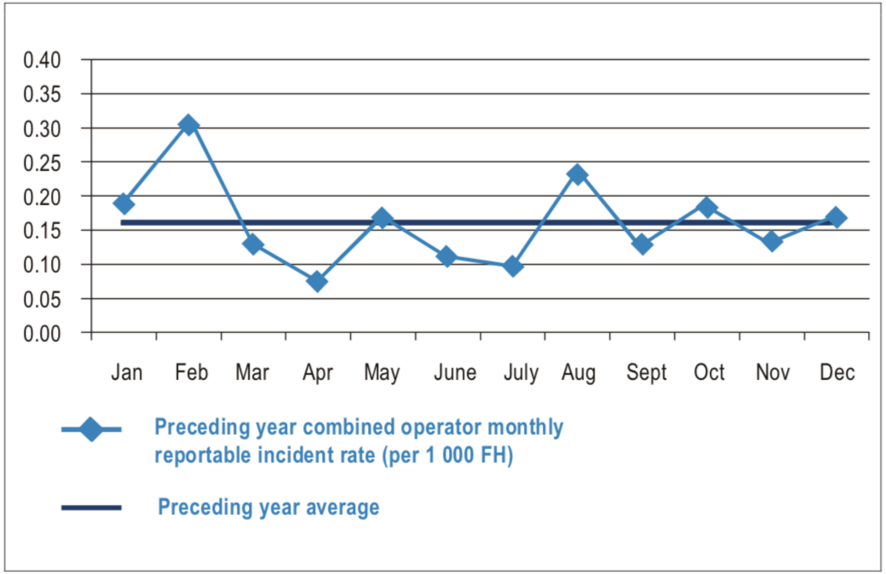
Category	Indicators
LOC-I: Loss of control - inflight	• Stick shaker • Increased roll attitude or rate • High pitch angle • Overspeed (vertical or configuration) • Failure of primary flight instruments
CFIT: Controlled flight into or toward terrain	• EGPWS hard warnings • Descent below MSA • Navigation errors
RE: Runway excursion	• Abnormal runway contact • Loss of control on ground • Long or fast landings • Occurrences with crosswind conditions • High speed rejected take-offs • ATA32 related occurrences
MAC: Airprox/ ACAS alert/ loss of separation/ (near) midair collisions	• Losses of separation • Inadequate separation • Level Busts • Airspace Infringement
RI-VAP: Runway incursion - vehicle, aircraft or person	• Runway Incursions
GCOL: Ground Collision and RAMP: Ground Handling	• Taxiway incursions • Avoiding manoeuvres during taxi • Aircraft collisions and collisions with aircraft
System Component Failure	• Engine failure • Flight control problems • Helicopter tail rotor and main rotor blade failures or malfunctions

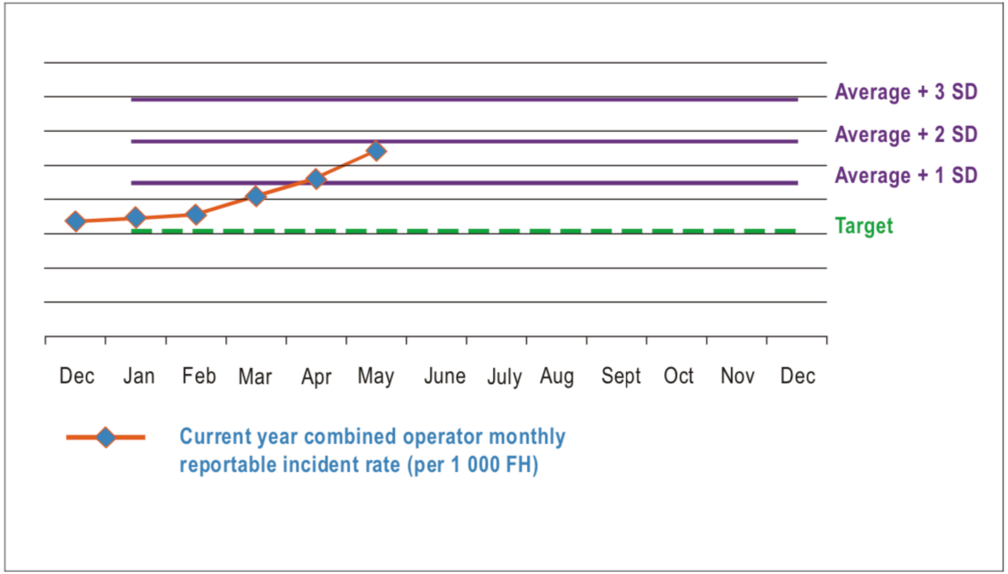
Calculation of the Alert levels

- The alert level setting is based on basic safety metrics standard deviation criteria.
- The Excel spreadsheet formula is ”=STDEVP”.
- For the purpose of standard deviation calculation, the formula is:

$$\sigma = \sqrt{\frac{\Sigma\,(x-\mu)^2}{N}}$$

Calculation of the Alert levels





Calculation of the Alert levels

a) Alert level setting:

The alert level for a new monitoring period (current year) is based on the preceding period's performance (preceding year), namely its data points average and standard deviation. The three alert lines are average + 1 SD, average + 2 SD and average + 3 SD.

b) Alert level trigger:

An alert (abnormal/unacceptable trend) is indicated if any of the conditions below are met for the current monitoring period (current year):

— any single point is above the 3 SD line
— 2 consecutive points are above the 2 SD line
— 3 consecutive points are above the 1 SD line.

When an alert is triggered (potential high risk or out-of-control situation), appropriate follow-up action is expected, such as further analysis to determine the source and root cause of the abnormal incident rate and any necessary action to address the unacceptable trend.

c) Target level setting (planned improvement):

The target level setting may be less structured than the alert level setting, e.g. target the new (current year) monitoring period's average rate to be say 5% lower (better) than the preceding period's average value.

d) Target achievement:

At the end of the current year, if the average rate for the current year is at least 5% or more lower than the preceding year's average rate, then the set target of 5% improvement is deemed to have been achieved.

e) Alert and target levels — validity period:

Alert and target levels should be reviewed/reset for each new monitoring period, based on the equivalent preceding period's average rate and SD, as applicable.

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Hazard Identification and Risk Assessment

Hazard

- A hazard is generically defined by safety practitioners as a condition or an object with the potential to cause death, injuries to personnel, damage to equipment or structures, loss of material, or reduction of the ability to perform a prescribed function.
- For the purpose of aviation safety risk management, the term hazard should be focused on those conditions which could cause or contribute to unsafe operation of aircraft or aviation safety-related equipment, products and services.

Hazard

- Hazards are an inevitable part of aviation activities. However, their manifestation and possible consequences can be addressed through various mitigation strategies to contain the potential for a hazard to result in unsafe aircraft or aviation equipment operations.
- Hazard identification is a prerequisite to the safety risk management process.
- Any incorrect differentiation between hazards and safety risks can be a source of confusion.
- A clear understanding of hazards and their related consequences is essential to the implementation of sound safety risk management.

Hazard identification and prioritization

- Hazards exist at all levels in the organization and are detectable through use of reporting systems, inspections or audits.
- Hazards should be identified before they lead to accidents, incidents or other safety-related occurrences.
- An important mechanism for proactive hazard identification is a voluntary hazard/incident reporting system.

Hazard identification and prioritization

- Hazards can also be identified from the review or study of investigation reports,
- Thus, a systematic procedure to review accident/incident investigation reports for outstanding hazards is a good mechanism to enhance an organization's hazard identification system.
- This is particularly relevant where an organization's safety culture is not sufficiently mature to support an effective voluntary hazard reporting system.

Hazard identification and prioritization

- The three methodologies for identifying hazards are:
- a) Reactive. This methodology involves analysis of past outcomes or events. Hazards are identified through investigation of safety occurrences.
- b) Proactive. This methodology involves analysis of existing or real-time situations, which is the primary job of the safety assurance function with its audits, evaluations, employee reporting, and associated analysis and assessment processes.
- c) Predictive. This methodology involves data gathering in order to identify possible negative future outcomes or events, analysing system processes and the environment to identify potential future hazards and initiating mitigating actions.

Safety Risk

- Safety Risk is a projected **likelihood** and **severity** of the consequence or outcome from an existing hazard or situation.
- The process of controlling safety risks starts by assessing the probability that the consequences of hazards will materialize during aviation activities performed by the organization.
- **Safety risk probability** is defined as the likelihood or frequency that a safety consequence or outcome might occur.

Safety Risk Probability

Likelihood	*Meaning*	*Value*
Frequent	Likely to occur many times (has occurred frequently)	5
Occasional	Likely to occur sometimes (has occurred infrequently)	4
Remote	Unlikely to occur, but possible (has occurred rarely)	3
Improbable	Very unlikely to occur (not known to have occurred)	2
Extremely improbable	Almost inconceivable that the event will occur	1

Safety risk severity

- Safety risk severity is defined as the **extent of harm** that might reasonably occur as a consequence or outcome of the identified hazard.
- The severity assessment can be based upon:
  - a) Fatalities/injury. How many lives may be lost (employees, passengers, bystanders and the general public)?
  - b) Damage. What is the likely extent of aircraft, property or equipment damage?
- The severity assessment should consider the worst foreseeable situation.

Safety Risk Severity

Severity	*Meaning*	*Value*
Catastrophic	— Equipment destroyed — Multiple deaths	A
Hazardous	— A large reduction in safety margins, physical distress or a workload such that the operators cannot be relied upon to perform their tasks accurately or completely — Serious injury — Major equipment damage	B
Major	— A significant reduction in safety margins, a reduction in the ability of the operators to cope with adverse operating conditions as a result of an increase in workload or as a result of conditions impairing their efficiency — Serious incident — Injury to persons	C
Minor	— Nuisance — Operating limitations — Use of emergency procedures — Minor incident	D
Negligible	— Few consequences	E

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Safety risk tolerability

- The third step in the process is to determine safety risk tolerability.
- First, it is necessary to obtain the indices in the safety risk assessment matrix.

Risk probability		Risk severity				
		Catastrophic A	Hazardous B	Major C	Minor D	Negligible E
Frequent	5	5A	5B	5C	5D	5E
Occasional	4	4A	4B	4C	4D	4E
Remote	3	3A	3B	3C	3D	3E
Improbable	2	2A	2B	2C	2D	2E
Extremely improbable	1	1A	1B	1C	1D	1E

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Safety risk tolerability

- Using the example above, if the criterion for safety risk is assessed as 4B, it falls in the —unacceptable category. The organization must therefore:
  - a) take measures to reduce the organization’s exposure to the particular risk, i.e. reduce the likelihood component of the risk index;
  - b) take measures to reduce the severity of consequences related to the hazard, i.e. reduce the severity component of the risk index; or
  - c) cancel the operation if mitigation is not possible.

Safety Risk Management

SAFETY RISK MANAGEMENT

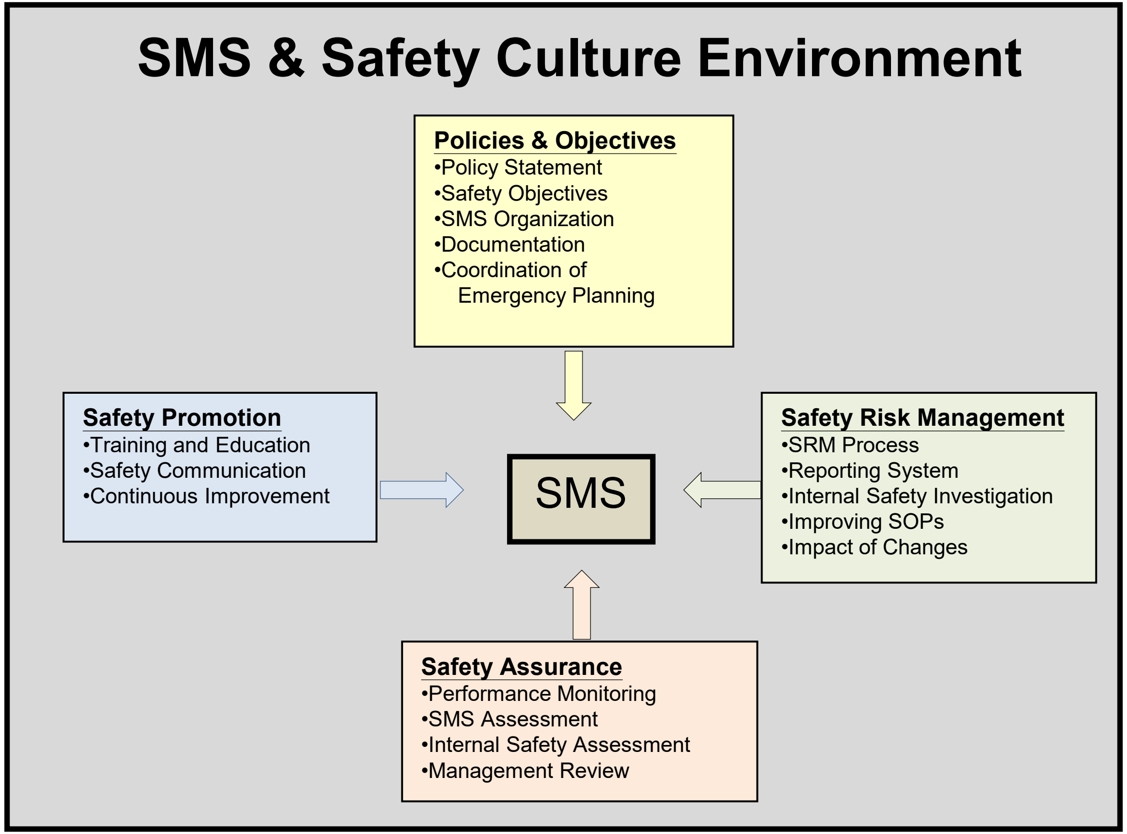
- Safety risk management encompasses the assessment and mitigation of safety risks. Safety risks are conceptually assessed as acceptable, tolerable or intolerable.
- Risks assessed as initially falling in the **intolerable region** are unacceptable under any circumstances. Immediate mitigation action is required.
- Safety risks assessed in the **tolerable region** are acceptable provided that appropriate mitigation strategies are implemented by the organization
- Safety risks assessed as initially falling in the **acceptable region** are acceptable as they currently stand and require no action to bring or keep the probability and/or severity of the consequences of hazards under organizational control.

SAFETY RISK MANAGEMENT

Tolerability description	Assessed risk index	Suggested criteria
Intolerable region	5A, 5B, 5C, 4A, 4B, 3A	Unacceptable under the existing circumstances
Tolerable region	5D, 5E, 4C, 4D, 4E, 3B, 3C, 3D, 2A, 2B, 2C, 1A	Acceptable based on risk mitigation. It may require management decision.
Acceptable region	3E, 2D, 2E, 1B, 1C, 1D, 1E	Acceptable

Four Components of SMS

Four Components of SMS



- SAFETY POLICY & OBJECTIVES
- SAFETY RISK MANAGEMENT
- SAFETY ASSURANCE
- SAFETY PROMOTION

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SSP/SMS Framework

- An SMS framework requires specific activities and processes that must be performed by aviation service providers. The ICAO SMS framework comprises the four following components as well as twelve underlying elements:
- a) safety policy and objectives;
- b) safety risk management;
- c) safety assurance; and
- d) safety promotion.

SSP Framework

- State safety policy and objectives
  - 1.1 State safety legislative framework
  - 1.2 State safety responsibilities and accountabilities
  - 1.3 Accident and incident investigation
  - 1.4 Enforcement policy
- State safety risk management
  - 2.1 Safety requirements for the service provider's SMS
  - 2.2 Agreement on the service provider's safety performance
- State safety assurance
  - 3.1 Safety oversight
  - 3.2 Safety data collection, analysis and exchange
  - 3.3 Safety-data-driven targeting of oversight of areas of greater concern or need
- State safety promotion
  - 4.1 Internal training, communication and dissemination of safety information
  - 4.2 External training, communication and dissemination of safety information.

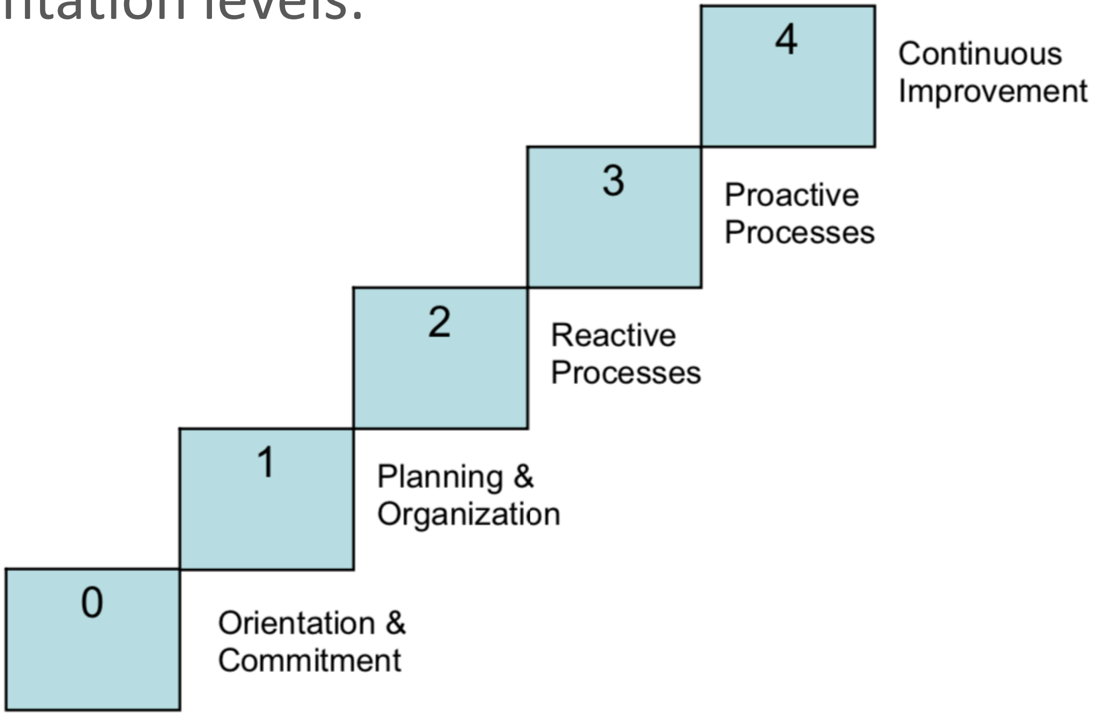
SMS Framework

- 1. Safety policy and objectives
  - 1.1 Management commitment and responsibility
  - 1.2 Safety accountabilities
  - 1.3 Appointment of key safety personnel
  - 1.4 Coordination of emergency response planning
  - 1.5 SMS documentation
- 2. Safety risk management
  - 2.1 Hazard identification
  - 2.2 Safety risk assessment and mitigation
- 3. Safety assurance
  - 3.1 Safety performance monitoring and measurement
  - 3.2 The management of change
  - 3.3 Continuous improvement of the SMS
- 4. Safety promotion
  - 4.1 Training and education
  - 4.2 Safety communication.

Implementation of SMS

Phased Approach to the SMS implementation

→ Implementation levels:



Implementation Level Zero: Orientation & Commitment

- **Level zero** is not so much a level as a status.
- It indicates that the service provider has not started formal SMS development or implementation and includes the time period between a service provider’s first request for information on SMS implementation and when the service provider’s top management commits to implementing an SMS.
- Level zero is a time for the service provider to gather information, evaluate corporate goals and objectives and determine committment of the resources to an SMS implementation effort.

Implementation Level One: Planning and Organization

- Level 1 begins when a service provider's top management commits to providing the resources necessary for full implementation of SMS through out the organization.
  - **Gap Analysis.** The first step in developing an SMS is for the service provider to analyze its existing programs, systems, and activities with respect to the SMS functional expectations found in the ***SMS Framework***.
  - **Implementation Plan.** Once the gap analysis has been performed, an implementation plan is prepared.

Implementation Level Two: Reactive Process, Basic Risk Management

- At level two, the service provider develops and implements a basic SRM process and plan, organize and prepare the organization for further SMS development.
- Information acquisition, processing, and analysis functions are implemented and a tracking system for risk control and corrective actions are established.
- At this phase, the service provider corrects known deficiencies in safety management practices and operational processes and develops an awareness of hazards and responds with appropriate systematic application of preventative or corrective actions.
- This allows the service provider to react to unwanted events and problems as they occur and develop appropriate remedial action.

Implementation Level Three: Proactive Processes, Looking Ahead

- Level 3 expects SRM to be applied to <u>initial design</u> of systems, processes, organizations, and products, development of operational procedures, and planned changes to operational processes.
- The activities involved in the SRM process involve careful analysis of systems and tasks involved; identification of potential hazards in these functions, and development of risk controls.
- The risk management process developed at level two is used to analyze, document, and track these activities.

Second Law of Thermodynamics and its importance for SMS

- Entropy (*S*) definitions:
  - 1. a thermodynamic quantity representing the unavailability of a system's thermal energy for conversion into mechanical work, often interpreted as the **degree of disorder or randomness in the system**.
  - 2**. lack of order or predictability; gradual decline into disorder**.
- the second law of thermodynamics implies that entropy always increases with time
- Our everyday human experience is that <u>ordered systems are not occuring spontaneusly out of disorder</u>. It always requires intelligent work to build ordered system.
- It is also our everyday experience that **if we don’t maintain complex ordered systems, they always decay into disorder**.

Implementation Level Four: Continuous Improvement, Continued Assurance

- The final level of SMS maturity is the continuous improvement level. Processes have been in place and their performance and effectiveness have been verified.
- The complete SA process, including continuous monitoring and the remaining features of the other SRM and SA processes are functioning.
- A major objective of a successful SMS is to attain and maintain this continuous improvement status for the life of the organization.

→ FAA guidance on the implementation of SMS

FAA: SMS Implementation Guide – Revision 3

SMS Development Chart			
Components, Elements and Processes should be completed by the indicated Level of Implementation	**Implementation Level**		
SMS Framework Expectation	**1**	**2**	**3**
Component 1.0 Safety Policy and Objectives		X	
Element 1.1 Safety Policy	X		
Element 1.2 Mgmnt Commitment and Safety Accountabilities	(*1)	X	
Element 1.3 Key Safety Personnel	X		
Element 1.4 Emergency Preparedness and Response		X	
Element 1.5 SMS Documentation and Records		X	
Component 2.0 Safety Risk Management (SRM)		(*3)	X
Element 2.1 Hazard Identification and Analysis		X	
Process 2.1.1 System and Task Analysis			X
Process 2.1.2 Identify Hazards		X	
Element 2.2 Risk Assessment and Control		X	
Process 2.2.1 Analyze Safety Risk		X	
Process 2.2.2 Assess Safety Risk		X	
Process 2.2.3 Control/Mitigate Safety Risk		X	
Component 3.0 Safety Assurance			X
Element 3.1 Safety Performance Monitoring and Measurement		X	
Process 3.1.1 Continuous Monitoring		X	
Process 3.1.2 Internal Audits by Operational Departments		X	
Process 3.1.3 Internal Evaluation		X	
Process 3.1.4 External Auditing of the SMS		X	
Process 3.1.5 Investigation		X	
Process 3.1.6 Employee Reporting and Feedback System		X	
Process 3.1.7 Analysis of Data		X	
Process 3.1.8 System Assessment		X	
Process 3.1.9 Preventive/Corrective Action		X	
Process 3.1.10 Management Review		X	
Element 3.2 Management of Change		(*3)	X
Element 3.3 Continual Improvement		X	
Component 4.0 Safety Promotion			X
Element 4.1 Competencies and Training			X
Process 4.1.1 Personnel Expectations (Competence)	(*2)		X
Process 4.1.2 Training		X	
Element 4.2 Communication and Awareness		X	

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ICAO Annex 19 Overview

ICAO Annex 19 - Overview

- CHAPTER 1 – Definitions
- CHAPTER 2 – Applicability
- CHAPTER 3 – State safety management responsibilities
- CHAPTER 4 – Safety management system (SMS)
- CHAPTER 5 – Safety data collection, analysis and exchange
- APPENDIX 1 –State safety oversight system
- APPENDIX 2 – SMS Framework
- ATTACHMENT A – SSP Framework
- ATTACHMENT B – Legal guidance for the protection of information from safety data collection and processing systems

Annex 19 - Contents

- CHAPTER 1 – Definitions
  - Includes definitions specific to the management of safety.
- CHAPTER 2 – Applicability
  - The Standards and Recommended Practices (SARPs) are applicable to safety management functions related to, or in direct support of, the safe operation of aircraft

Annex 19 - Contents

- CHAPTER 3 – State Safety Management Responsibilities
  - This chapter outlines safety management responsibilities directly applicable to the State, including the SMS requirements be implemented by the following service providers* (as described in the relevant Annexes):
    - 1. Approved training organizations;
    - 2. Operators of aeroplanes or helicopters authorized to conduct international
    - commercial air transport;
    - 3. Approved maintenance organizations providing services to operators as described in bullet 2;
    - 4. Organizations responsible for the type design or manufacture of aircraft;
    - 5. Air traffic services (ATS) providers, and;
    - 6. Operators of certified aerodromes.

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Annex 19 - Contents

- CHAPTER 3 – State Safety Management Responsibilities (cont.)
- In particular, it addresses the elements of the State Safety Programme (SSP) and the State safety oversight Standards, respectively described in Attachment A (SSP framework) and Appendix 1 (State safety oversight system).

Four Components of SMS are ICAO Standard

- The following four components of the SSP framework were elevated to the status of Standard in chapter 3:
  - State Safety policy and objectives
  - State Safety Risk Management
  - State Safety assurance
  - State Safety promotion

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Annex 19 - Contents

- → CHAPTER 4 – Safety Management System (SMS)
- → Outlines the safety management responsibilities of service providers, described in Appendix 2 (SMS framework);
- → Also includes the safety management responsibilities of international general aviation operators, conducting operations of large or turbojet aeroplanes.

Annex 19 - Contents

- CHAPTER 5–Safety Data Collection, Analysis and Exchange
- Outlines the specifications to support safety management activities by collection and analysis of safety data and by exchange of safety information, as part of the SSP.
- Complemented by Attachment B - Legal guidance for the protection of information from safety data collection and processing systems.

Annex 19 - Contents

- → CHAPTER 5–Safety Data Collection, Analysis and Exchange
- → Outlines the specifications to support safety management activities by collection and analysis of safety data and by exchange of safety information, as part of the SSP.
- → Complemented by Attachment B - Legal guidance for the protection of information from safety data collection and processing systems.

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End of presentation

Thank you for your attention!