



Risk Based Oversight and Surveillance Workshop

Joachim Wirths & Peter Wilczek, OPS & PEL Experts

6-7 February 2020

Bangkok, Thailand

EU-South East Asia Aviation Partnership Project (EU-SEA APP)

*This project is funded by the European Union and implemented
by the European Union Aviation Safety Agency - EASA*

Your safety is our mission.

An Agency of the European Union



Introduction Lecturer H.J.Wirths - MSAE

- Pilot since 1977
- Still active Captain, TRI and TRE on EMB 190 Jet
- CAA Inspector
- CAA Manager
- EASA Standards
- Aviation Expert (Dipl. Univ. Karlsruhe) ISO 17024 Certified Aviation Expert
- Accident Investigator
- Aviation Auditor (IOSA, ISO, ISAGO)
- EASA Expert # 376 (2016) # 10115 (2019)



Main Task during the stay → Lecturer

Introduction Lecturer P. Wilczek - MBA MAE

- 25+ years in aviation
- Captain on CRJ 200, LJ 20/30, Flight Instructor
- Senior Flight Examiner (Astro Control)
- Aviation Expert Diploma
- Member of the German Association of Aviation Experts (VdL)
- ISO 17024 Certified Aviation Expert
- ICAO Training Developer
- IOSA Auditor
- Speaker at several international aviation summits
- EASA Expert # 10224

Main Task during the stay → Lecturer



Course Schedule

- 08:30 – 09:30 – Session activity
- 10:00 – 10:30 – **Coffee/Tea break**
- 10:30 – 11:15 – Session activity
- 11:15 – 12:30 – Session activity
- 12:30 – 13:30 – **Lunch**
- 13:30 – 15:00 – Session activity
- 15:00 – 15:30 – **Coffee/Tea break**
- 15:30 – 17:30 – Session activity



Introduction Participants

The 5 W's

- **Who** are you ?
 - What is your preferred name in class?
- **Where** do you work?
- **What** is your job title?
- **What** are your main responsibilities?
- **Why** are you attending this course?
 - Please define your expectations

Objectives

- How to measure an Entity to determine baseline oversight levels.
- Identification of the key components of a risk-based oversight audit cycle.
- The importance of the collaboration between the Entity oversight team members to fully determine the risk picture.
- Analytical techniques used to produce safety performance indicators to monitor trends and identify risks.
- The fundamental principles of risk measuring and the importance it plays in RBO.
- The concept of varying future oversight based on risk and performance profiles.

Where are we now ?



PAST = QM / SMS was a burden..... 😞

PRESENT = QM / SMS is established as beneficial tool... 😊
Only a few NAAs could manage to establish a working SSP... 😞

FUTURE = **SMS** will be used as acceptable tool achieving tailored needs of an operator within a more and more standardised aviation safety system. 😊
SSP could be the ultimate tool managing regulatory **risk-based** oversight. 😊

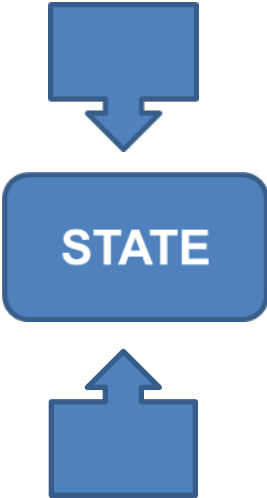
Safety Performance



Present Status



INTERNATIONAL AVIATION OVERSIGHT ORGANIZATIONS



AVIATION INDUSTRY



Three Challenging Cultures



ICAO Annex 19



International Standards
and Recommended Practices



Annex 19
to the Convention on
International Civil Aviation

Safety Management



CHAPTER 2. APPLICABILITY

The Standards and Recommended Practices contained in this Annex shall be applicable to safety management functions related to, or in direct support of, the safe operation of aircraft.

Note 1.— Safety management provisions for States are contained in Chapter 3 and relate to a State safety programme.

Note 2.— Safety management provisions for specified aviation service providers and operators are in Chapter 4 and relate to safety management systems (SMSs). Supplementary safety management provisions specific to individual service providers or operators are contained in other Annexes, as referenced in this Annex.

State Safety Programme (SSP)

3.1 State safety programme (SSP)

3.1.1 Each State shall establish an SSP for the management of safety in the State, in order to achieve an acceptable level of safety performance in civil aviation. The SSP shall include the following components:

- a) State safety policy and objectives;
- b) State safety risk management;
- c) State safety assurance; and
- d) State safety promotion.

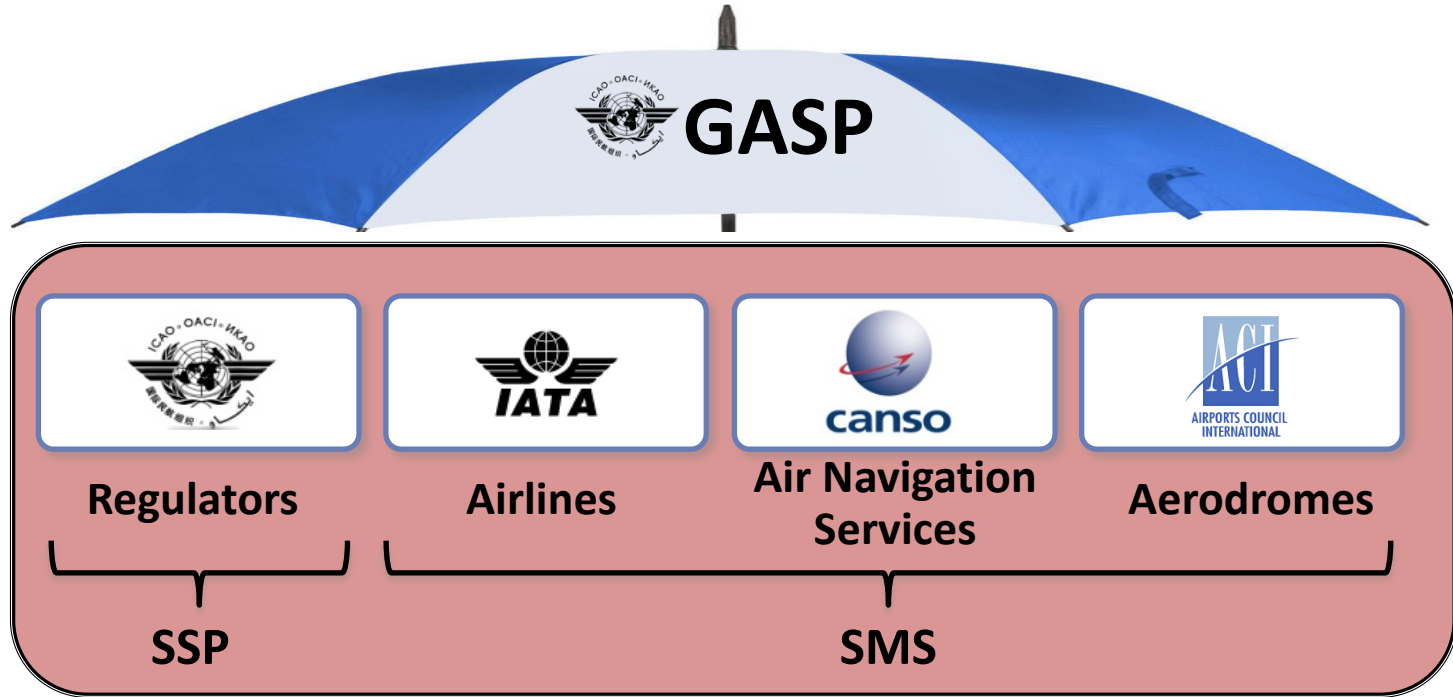
Note 1.— The SSP established by the State is commensurate with the size and the complexity of its aviation activities.

Note 2.— A framework for the implementation and maintenance of an SSP is contained in Attachment A, and guidance on a State safety programme is contained in the Safety Management Manual (SMM) (Doc 9859).

3.1.2 The acceptable level of safety performance to be achieved shall be established by the State.

Note.— Guidance on defining an acceptable level of safety performance is contained in the Safety Management Manual (SMM) (Doc 9859).

GASP – Global Aviation Safety Plan



ICAO Global Safety Strategy: GASP – Global Aviation Safety Plan 2017-19

Safety performance enablers	Effective safety oversight	SSP implementation	Predictive risk management
Standardization	RASGs and other fora: mechanisms for sharing of safety information	RASGs: mature regional monitoring and safety management programmes	All States: implement advanced safety oversight systems, including predictive risk management
Resources	States with EI > 60%: SSP implementation	All States: SSP implementation	
Collaboration	All States: achieve 60% EI of CEs		
Safety information exchange			



SECTION III

Air operations

Article 29

Essential requirements

The **operation of aircraft**, other than unmanned aircraft, shall comply with the essential requirements set out in **Annex V** and, if applicable, Annexes VII and VIII.

Annex V

8.1. The operation must not be undertaken unless the following conditions are met:

- (d) the aircraft operator shall **establish an occurrence reporting system, as part of the management system**, in order to contribute to the aim of continuous improvement of the safety. The occurrence reporting system shall be compliant with applicable Union law.

Annex V

8.7. The prevention of fatigue must be managed through a **fatigue management system**. For a flight, or series of flights, such a system needs to address **flight time, flight-duty periods, duty and adapted rest periods**. Limitations established within the fatigue management system must **take into account all relevant factors contributing to fatigue** such as, in particular, number of sectors flown, time-zone crossing, sleep deprivation, disruption of circadian cycles, night hours, positioning, cumulative duty time for given periods of time, sharing of allocated tasks between crew members, and also the provision of augmented crews.

Part ARO

EU Regulation 965/2012 – Part ARO

ARO.GEN.115 Oversight documentation

The competent authority **shall provide all legislative acts, standards, rules, technical publications** and related documents to relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

EU Regulation 965/2012 – Part ARO

ARO.GEN.135 Immediate reaction to a safety problem

- (a) The competent authority **shall implement a system** to appropriately collect, analyse and disseminate safety information.
- (b) The Agency shall implement a system to appropriately analyse any relevant safety information received and without undue delay provide to Member States and the Commission any information, including recommendations or corrective actions to be taken, necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations.

EU Regulation 965/2012 – Part ARO

ARO.GEN.135 Immediate reaction to a safety problem

- (c) Upon receiving the information referred to in (a) and (b), **the competent authority shall take adequate measures** to address the safety problem.
- (d) Measures taken under (c) shall immediately be notified to all persons or organisations which need to comply with them under the Basic Regulation and its Implementing Rules. The competent authority shall also notify those measures to the Agency and, when combined action is required, the other Member States concerned.

EU Regulation 965/2012 – Part ARO

ARO.GEN.200 Management system

- (a) The competent authority shall establish and maintain a **management system, including** as a minimum:
- (1) **documented policies and procedures** to describe its organisation, means and methods to achieve compliance with the Basic Regulation and its Implementing Rules. The **procedures shall be kept up to date and serve as the basic working documents** within that competent authority for all related tasks;

EU Regulation 965/2012 – Part ARO

ARO.GEN.200 Management system

- (2) a **sufficient number of personnel to perform its tasks and discharge its responsibilities**. Such personnel shall be **qualified to perform their allocated tasks** and have the necessary **knowledge, experience, initial and recurrent training** to ensure continuing competence. A **system** shall be in place **to plan the availability of personnel**, in order to ensure the proper completion of all tasks;
- (3) **adequate facilities and office accommodation** to perform the allocated tasks;

EU Regulation 965/2012 – Part ARO

ARO.GEN.200 Management system

- (4) a **function to monitor compliance** of the management system with the relevant requirements and adequacy of the procedures including the establishment of an **internal audit process and a safety risk management process**. Compliance monitoring shall include a feedback system of audit findings to the senior management of the competent authority to ensure implementation of corrective actions as necessary; and
- (5) a person or group of persons, **ultimately responsible to the senior management** of the competent authority **for the compliance monitoring function**.

EU Regulation 965/2012 – Part ARO

ARO.GEN.200 Management system

- (b) The competent authority shall, **for each field of activity**, including management system, appoint **one or more persons with the overall responsibility for the management** of the relevant task(s).

EU Regulation 965/2012 – Part ARO

ARO.GEN.200 Management system

- (c) The competent authority shall establish **procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities** concerned including on all findings raised and follow-up actions taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State, but certified or authorised by or making declarations to the competent authority of another Member State or the Agency.
- (d) A copy of the **procedures related to the management system and their amendments shall be made available to the Agency** for the purpose of standardisation.

EU Regulation 965/2012 – Part ARO

ARO.GEN.300 Oversight

(a) The competent authority shall verify:

- 1) **compliance with the requirements** applicable to organisations or type of operations prior to the issue of a certificate, approval or authorisation, as applicable;
- 2) **continued compliance** with the applicable requirements of organisations it has certified, specialised operations it has authorised and organisations from whom it received a declaration;
- 3) **continued compliance** with the applicable requirements of non-commercial operators of other-than complex motor-powered aircraft; and

EU Regulation 965/2012 – Part ARO

ARO.GEN.300 Oversight

- 4) **implementation of appropriate safety measures** mandated by the competent authority as defined in ARO.GEN.135(c) and (d).

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

- (a) The competent authority shall establish and **maintain an oversight programme** covering the oversight activities required by ARO.GEN.300 and by ARO.RAMP.

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

(b) For organisations certified by the competent authority, the oversight programme shall be developed taking into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities required by ARO.GEN and ARO.RAMP and shall be based on the assessment of associated risks. It shall include within each oversight planning cycle:

- 1) audits and inspections, including ramp and unannounced inspections as appropriate; and
- 2) meetings convened between the accountable manager and the competent authority to ensure both remain informed of significant

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

(c) For organisations certified by the competent authority an oversight planning cycle not exceeding 24 months shall be applied.

The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

The oversight planning cycle may be extended to a maximum of 36 months if the competent authority has established that, during the previous 24 months:

- 1) the organisation has demonstrated an effective identification of aviation safety hazards and management of associated risks;

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

- 2) the organisation has continuously demonstrated under ORO.GEN.130 that it has full control over all changes;
- 3) no level 1 findings have been issued; and

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

- 4) all corrective actions have been implemented within the time period accepted or extended by the competent authority as defined in ARO.GEN.350(d)(2).

The oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the above, the organisation has established, and the competent authority has approved, an effective continuous reporting system to the competent authority on the safety performance and regulatory compliance of the organisation itself.

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

- (d) For organisations declaring their activity to the competent authority, the oversight programme shall be based on the specific nature of the organisation, the complexity of its activities and the data of past oversight activities and the assessment of risks associated with the type of activity carried out. It shall include audits and inspections, including ramp and unannounced inspections, as appropriate.
- (d1) For organisations holding a specialised operations authorisation, the oversight programme shall be established in accordance with (d) and shall also take into account the past and current authorisation process and the validity period of the authorisation.

EU Regulation 965/2012 – Part ARO

ARO.GEN.305 Oversight programme

- (e) For persons holding a licence, certificate, rating, or attestation issued by the competent authority the oversight programme shall include inspections, including unannounced inspections, as appropriate.
- (f) The oversight programme shall include records of the dates when audits, inspections and meetings are due and when such audits, inspections and meetings have been carried out.

Part ORO

EU Regulation 965/2012 – Part ORO

ORO.GEN.200 Management system

- (a) The operator shall establish, implement and maintain a management system that includes:
- 1) clearly defined lines of responsibility and accountability throughout the operator, including a direct safety accountability of the accountable manager;
 - 2) a description of the overall philosophies and principles of the operator with regard to safety, referred to as the safety policy;
 - 3) the identification of aviation safety hazards entailed by the activities of the operator, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;

EU Regulation 965/2012 – Part ORO

ORO.GEN.200 Management system

- 4) maintaining personnel trained and competent to perform their tasks;
- 5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;
- 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; and

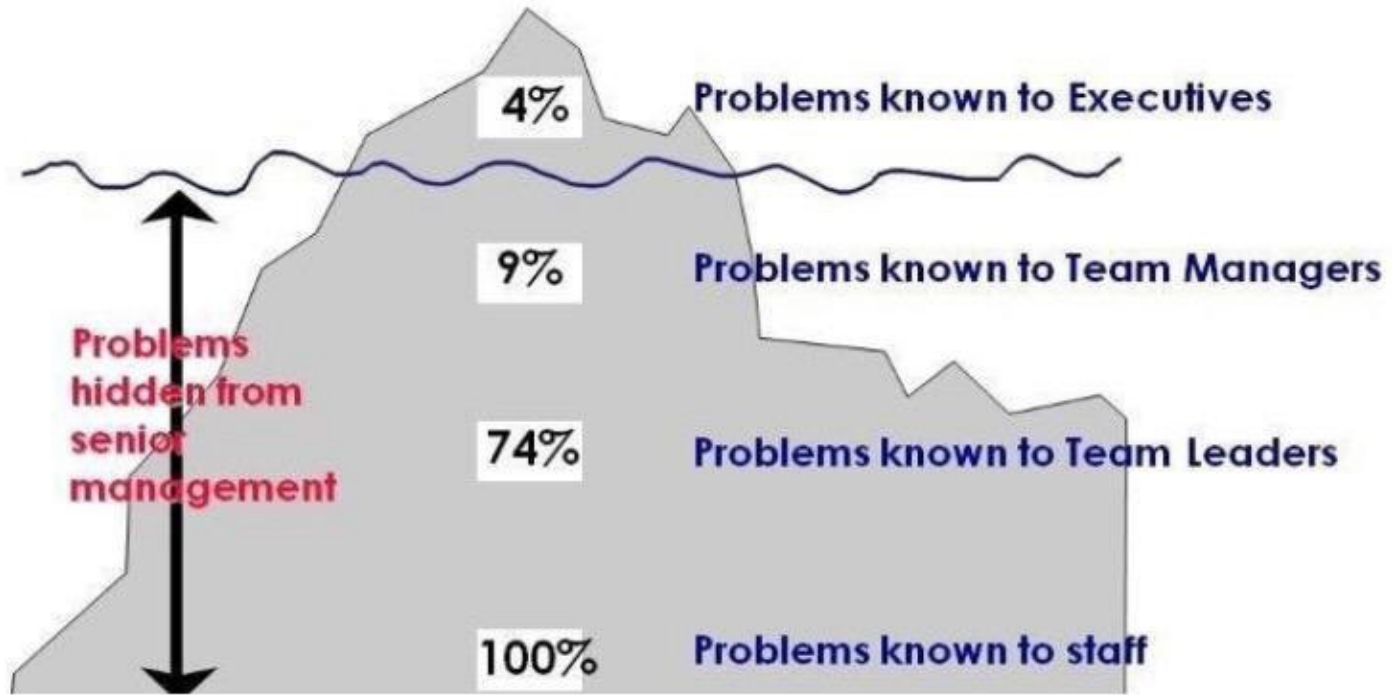
EU Regulation 965/2012 – Part ORO

ORO.GEN.200 Management system

- 7) any additional requirements that are prescribed in the relevant Subparts of this Annex or other applicable Annexes.
- (b) The management system shall correspond to the size of the operator and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

Management System

The Iceberg of Ignorance



5 P's ...

➤ **POLICY** → Vision and Mission set by highest management

➤ **PLAN** → Target Achievements, business plan resources

Question: What is management?

Management is changing given resources into positive results!

➤ **PEOPLE** (Roles and Positions)

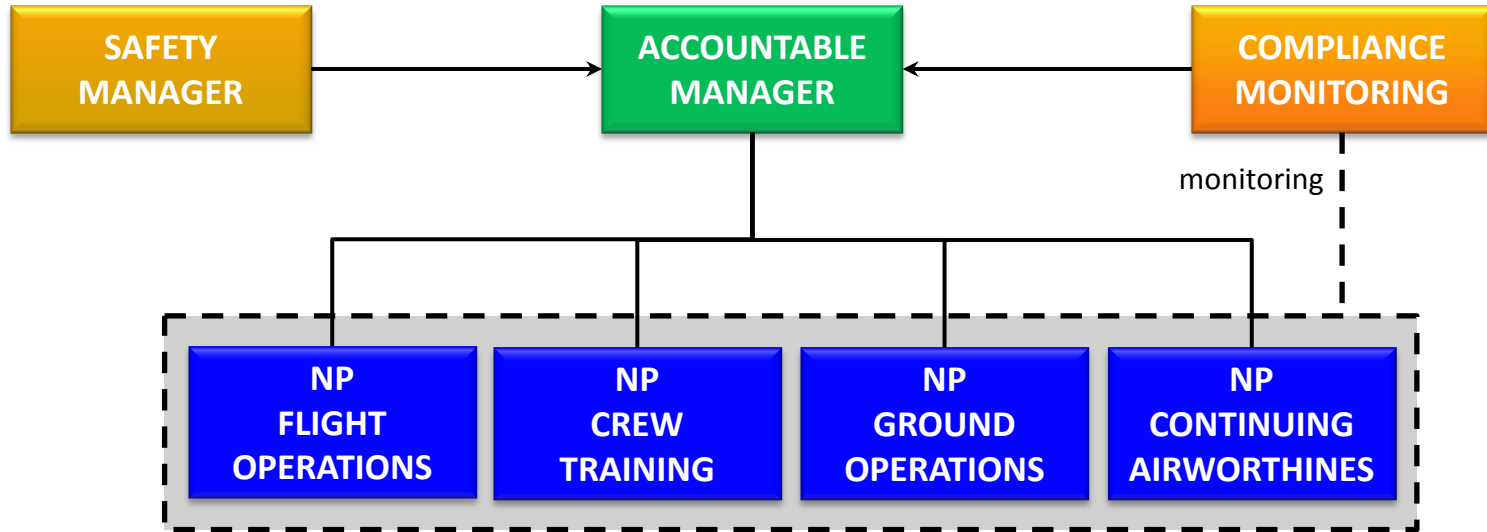
➤ **PROCESSES** → Core and sub process design and controlled documents

➤ **PROCEDURES** → needed to run processes as defined

➤ **Guideline: ISO 9001**

➤ *Recommended: Establishment of an associated Process and Procedure Manual*

Standard Organigram (OPS)

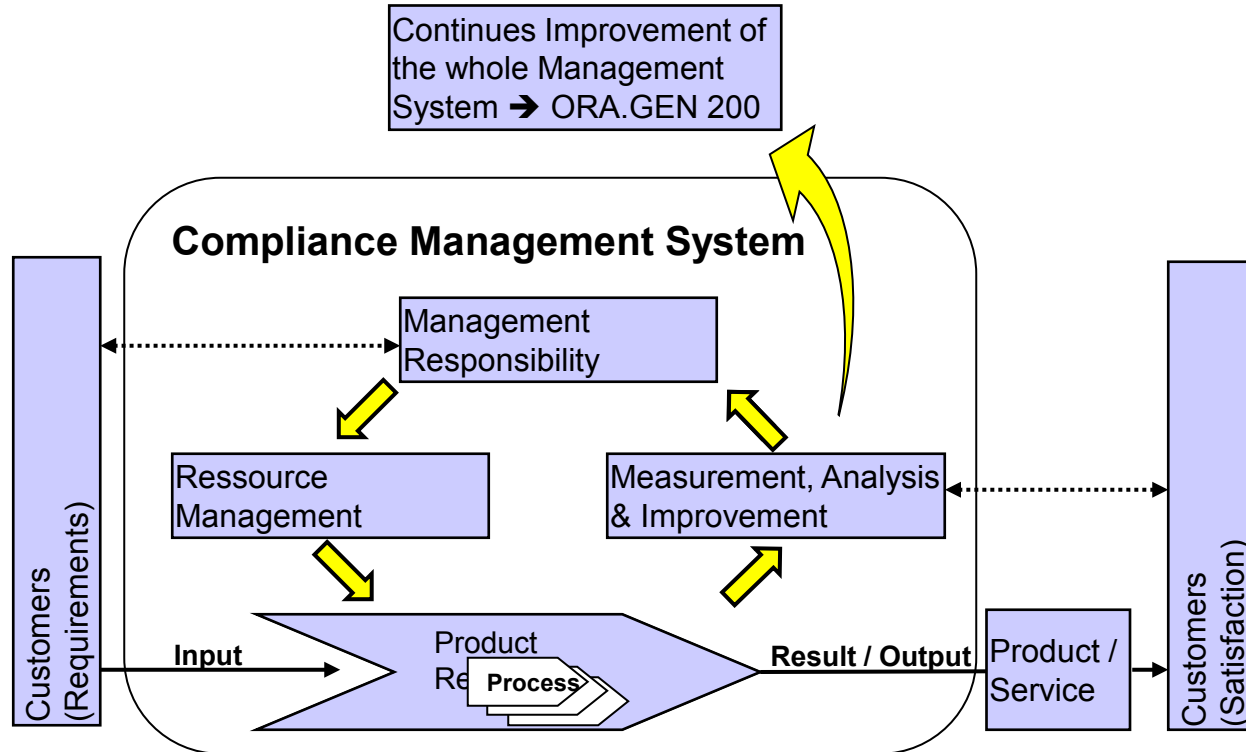


3rd P → Roles and Positions

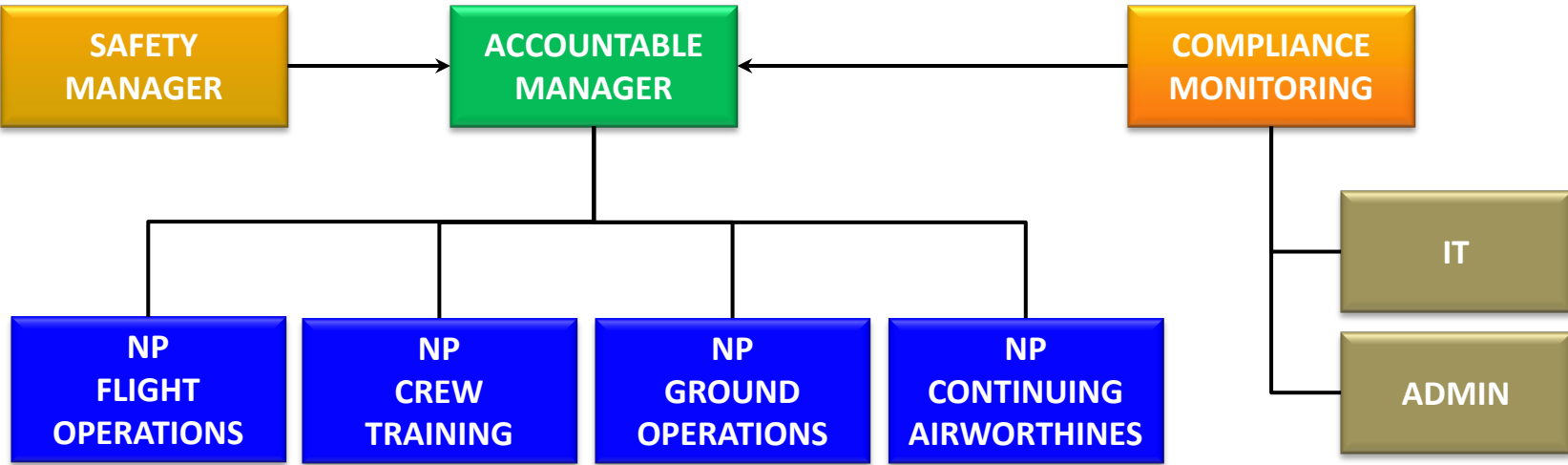
- Step 1 → Define **clear and functional competence-based roles** for people working for the organisation
- Step 2 → Define **clear Job Tasks and** create associated **Job descriptions** for all relevant positions within the organisation (Who is doing what and how)
- Step 3 → **Assign** competent Staff **to defined roles** (nominated persons, admin staff)
- Step 4 → Establish competence based **initial & recurrent training program** for staff
- Step 5 → Perform personal and competence **GAP Analysis for each staff member**, means documented competence as shown via CV and certificates versus additional training required for fulfillment of Job Tasks as noted in Job descriptions

Most important → NO PERSONAL AGENDAS, NO CONFLICT OF INTEREST

ISO 9001: Revision 2015



Proposed Organigram (OPS)



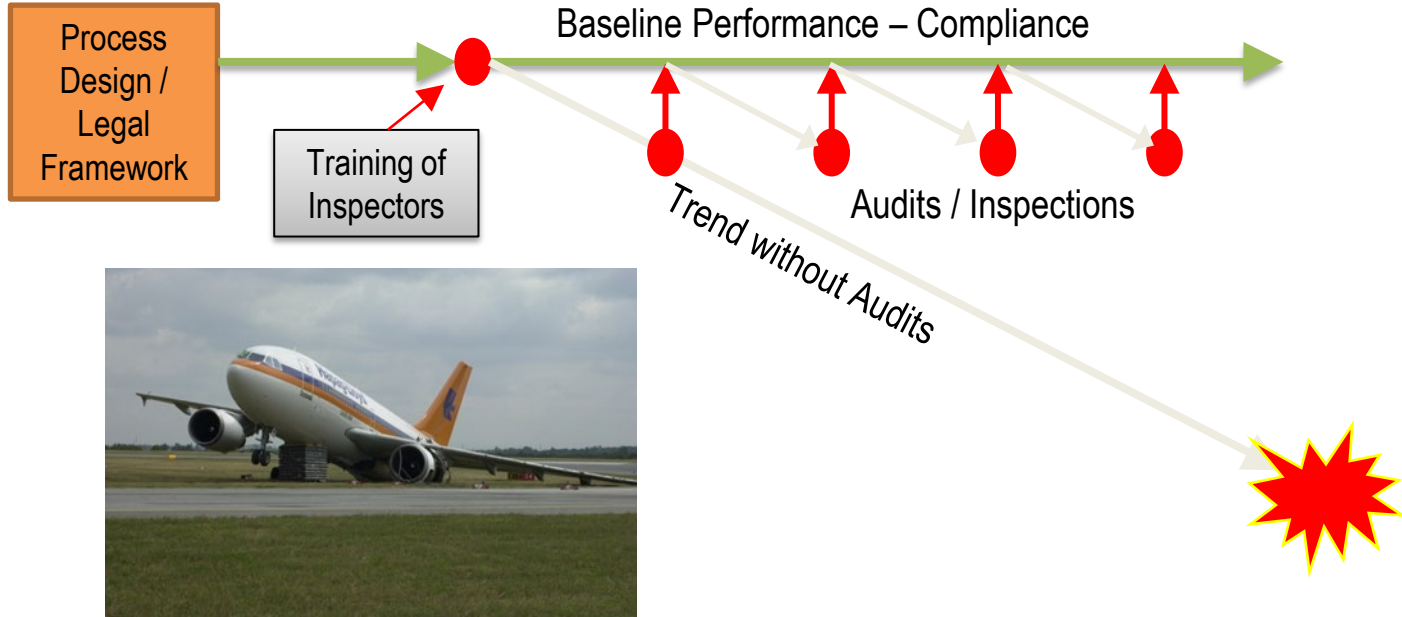
Safety Culture

Top Level Definition:

“Safety Culture is the set of enduring values and attitudes regarding safety, shared by every member of every level of an organization.”

COMPLIANCE MANAGEMENT

Compliance based Oversight – Approach



Fundamental Standards

The implementation and use of a compliance monitoring system enables the operator to **monitor compliance** with the relevant requirements of:

- legal provisions,
- the operator's manuals (OM, etc.), and
- any other standards as established by the operator, or the competent authority

The target of the compliance monitoring system is a **continuous improvement of the operator's processes**.

Fundamental Standards

Organisations should **monitor compliance with the procedures they have designed** to ensure safe activities.

In doing so, they should **as a minimum**, and where appropriate, **monitor** compliance with:

- privileges of the operator;
- manuals, logs, and records;
- training standards;
- management system procedures and manuals.

Fundamental Standards

The operator should **specify the basic structure of the compliance monitoring function** applicable to the activities conducted.

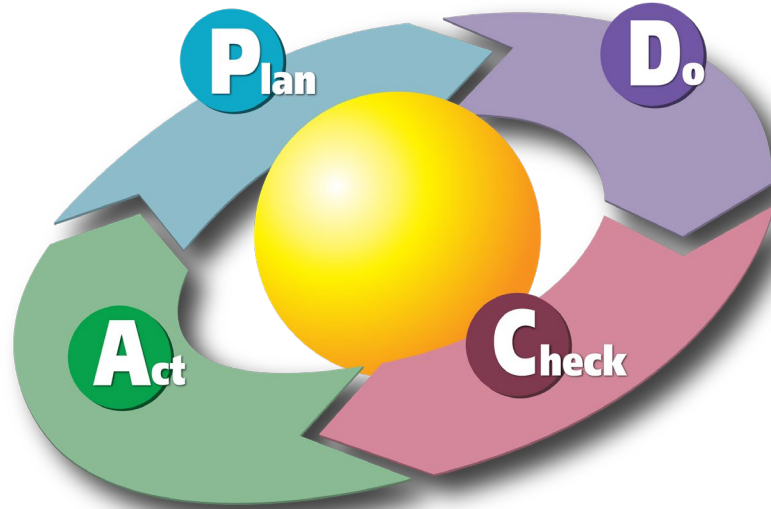
The compliance monitoring function should be **structured according to the size of the operator** and the complexity of the activities to be monitored.

Fundamental Standards

The strategy is based on the so-called “**PDCA-cycle**” through which the continuous improvement should be achieved:

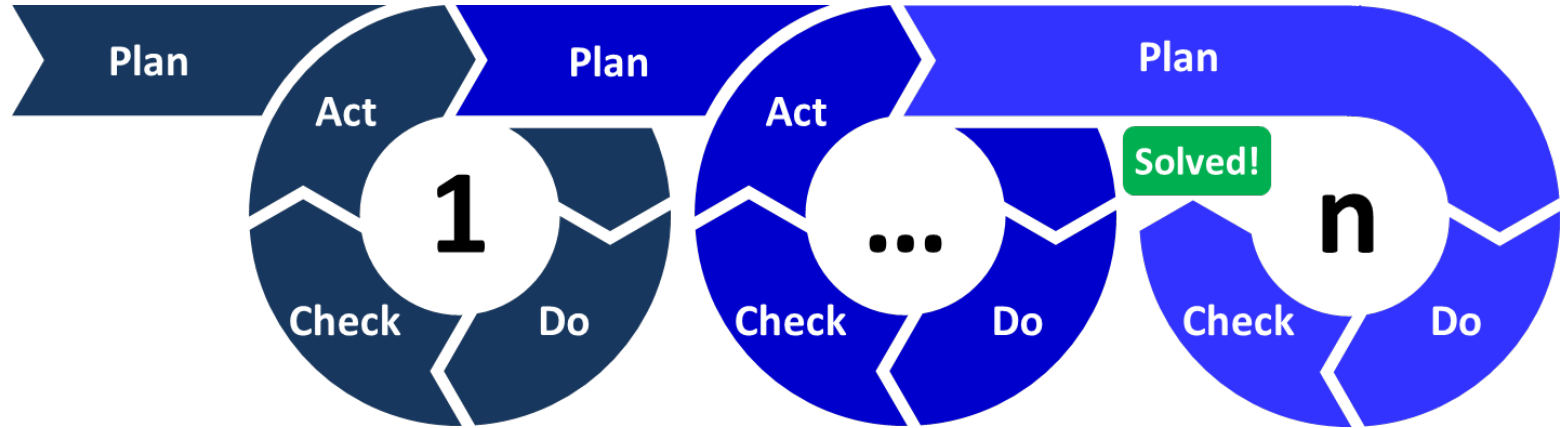
- **Plan:** Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organisation’s policies.
- **Do:** Implement the process.
- **Check:** Monitor and evaluate the processes and results against the specifications and report the outcome
- **Act:** Apply actions to the outcome for necessary improvement.

Fundamental Standards



→ **PDCA** (and other forms of scientific problem solving) is also known as a system for **developing critical thinking**.

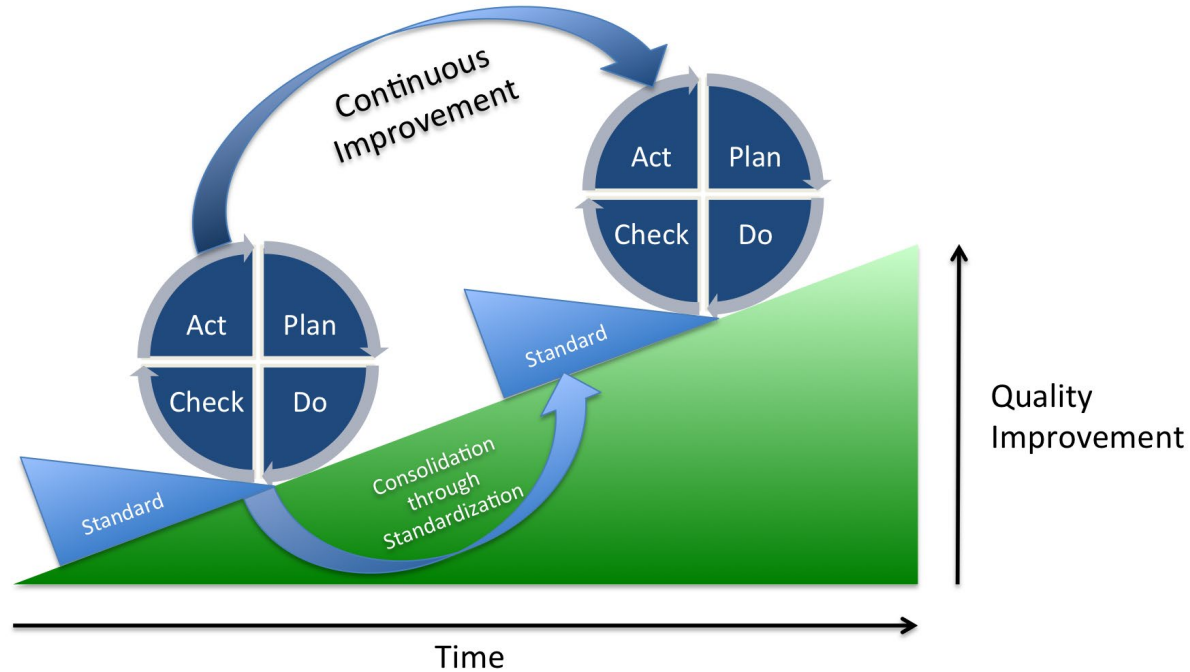
Fundamental Standards



Multiple iterative loops of a PDCA (plan, do, check act) cycle, also known as Deming Cycle.

The loops are **repeated until the problem is solved**.

Fundamental Standards



Continuous improvement is achieved by iterating through the cycle and **consolidating achieved progress through standardization.**

Compliance Monitoring Manager

The **AM** should designate a compliance monitoring manager.

The role of the CM is to **verify, by monitoring activities** in the field of operation, **that the standards required** by the competent authority, and any additional requirements as established by the operator, **are being carried out properly**.

The CM is **responsible for** ensuring that **the compliance monitoring programme** is properly implemented, maintained and continually reviewed and improved.

The CM is **ultimately responsible to the AM**.

Compliance Monitoring Manager

The **CM** should:

- **have direct access to the AM;**
- be able to **demonstrate relevant knowledge, background and appropriate experience** related to the activities of the operator, including knowledge and experience in compliance monitoring; and
- **have access to all parts of the operator**, and as necessary, any contracted operator.

Compliance monitoring documentation

Relevant documentation should **include the relevant part(s) of the operator's management system documentation.**

In addition, relevant documentation should also include the following:

- terminology;
- specified activity standards;
- a description of the operator;
- the allocation of duties and responsibilities;
- procedures to ensure regulatory compliance;

Compliance monitoring documentation

- the compliance monitoring programme, reflecting:
 - schedule of the monitoring programme;
 - audit procedures;
 - reporting procedures;
 - follow-up and corrective action procedures; and
 - recording system.
- the training syllabus;
- document control.

Audits & Inspections

The **main task** of the compliance monitoring system for the improvement is performing **internal audits** and **inspections**.

Audit – means a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which requirements are complied with.

Inspection – means an independent documented conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging, in order to verify compliance with applicable requirements.

Audits & Inspections

Both, an audit and an inspection are a **systematic** and **independent** comparison of the way, in which an operation is being conducted against the way, in which the published procedures say, it should be conducted.

An **overall or systemic assessment** implies that all locations, all stations, across all fleets, departments and operational functions, both within and throughout the operator's organization are audited.

The Compliance Monitoring Manager may perform all audits and inspections **himself or** appoint one or more **auditors** by choosing personnel having the related competence, either **from within or outside** the organisation.

Audit Plan

The CM shall **establish an audit plan** i.a.w. the procedures and within the time frames defined in the applicable OM.

The audit plan shall ensure that **all areas** of the operator are **audited within a 12-month period**.

The audit plan should be **approved by the AM**.

Department	Month											
	01/2019	02/2019	03/2019	04/2019	05/2019	06/2019	07/2019	08/2019	09/2019	10/2019	11/2019	12/2019
Flight Ops	#154 ORO. AOC.MLR [REDACTED]	#155 SPA.GEN SPA.PBN [REDACTED]	#153 ORO.SEC LSP [REDACTED]	#181 ORO GEN (Part-1) [REDACTED]	#174 ORO.FC [REDACTED]	#194 CAT.POL MAB [REDACTED]	#178 CAT.OP. MPA (Part-1) [REDACTED]	#196 CAT.IDE [REDACTED] (+Part M Subparts)	#173 CAT.IDE [REDACTED] (+Part M Subparts)	#193 CAT.GEN MPA [REDACTED]	#198 CAT.IDE [REDACTED] (+Part M Subparts)	#157 NCC [REDACTED]
Flight Ops	#156 ORO.FTL Sub Q & DvLuffBO [REDACTED]	#191 SPA.LVO MNPS RVSM [REDACTED]	#192 SPA.DG [REDACTED]	#217 ORO GEN (Part-2) [REDACTED]			#214 CAT.OP. MPA (Part-2) [REDACTED]	#213 ORO.SEC LSP [REDACTED]	#197 CAT.IDE [REDACTED] (+Part M Subparts)			
Part M	#137 Subpart B [REDACTED]			#168 Subpart C [REDACTED]				#169 Subpart G <i>Siegerland</i>			#171 Subpart I <i>Siegerland</i>	
Subcontractor					#218 Part 145 [REDACTED] (+Part M Subparts)	#212 Part 145 [REDACTED] (+Part M Subparts)				#215 [REDACTED]	#216 Fuel [REDACTED]	

Compliance Monitoring Manager

Accountable Manager

Audit & Inspection Preparation

Audit Preparation:

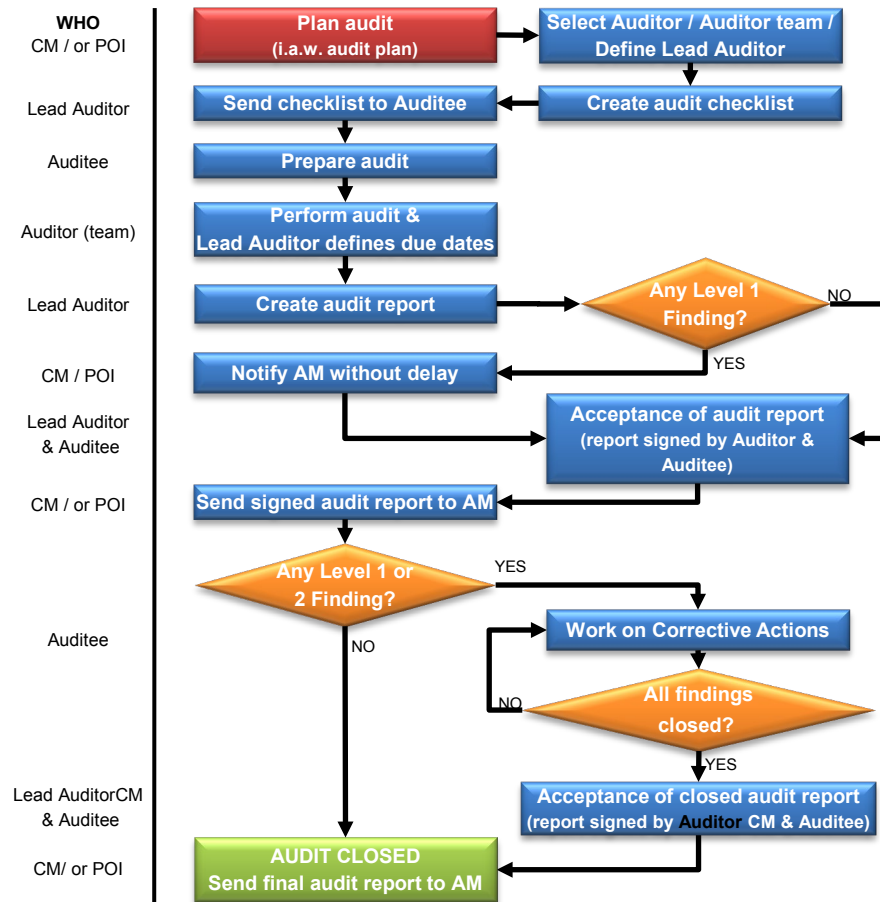
- Based on the complexity of the audit planned, decide whether a **Single Auditor** or an **Audit Team** is required.
- **Select Auditor(s)**
- In case of an Audit Team select a **Lead Auditor**
- Create the **audit questionnaire/checklist**
- **Send to Auditee** the audit questionnaire/checklist
- **Review** audit questionnaire/checklist returned by the Auditee (if applicable)

Audit & Inspection Preparation

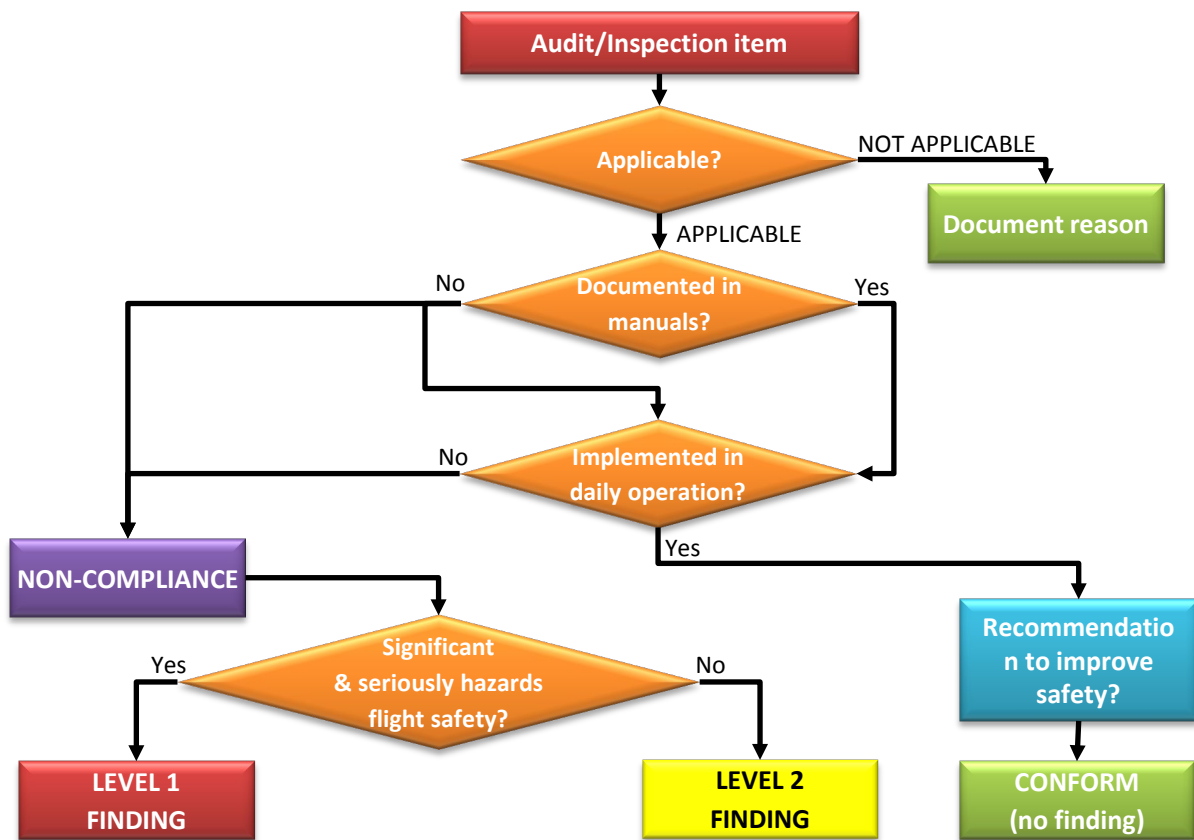
Inspection Preparation:

- Based on the complexity of the inspection planned, decide whether a **Single Auditor** or an **Audit Team** is required.
- **Select Auditor(s)**
- In case of an Audit Team select a **Lead Auditor**
- Create the **inspection questionnaire/checklist**

Audit Process



Perform an audit item/question



Corrective Action

Corrective action is the action to **eliminate or mitigate the root cause(s)** and **prevent recurrence** of an existing detected non-compliance or other undesirable condition or situation.

Proper determination of the **root cause** is crucial for defining effective corrective actions.

Corrective Action

Root cause analysis – 5-Why

5 Why is an **iterative interrogative technique** used to **explore the cause-and-effect relationships** underlying a particular problem.

Primary goal is to determine the root cause of a defect or problem by **repeating the question "Why?"**.

Each answer forms the basis of the next question.

The "5" in the name derives from an anecdotal observation on the number of iterations needed to resolve the problem.

Corrective Action

Root cause analysis – 5-Why

Example:

The engine will not start (= the problem)

Why? – The aircraft battery is dead.

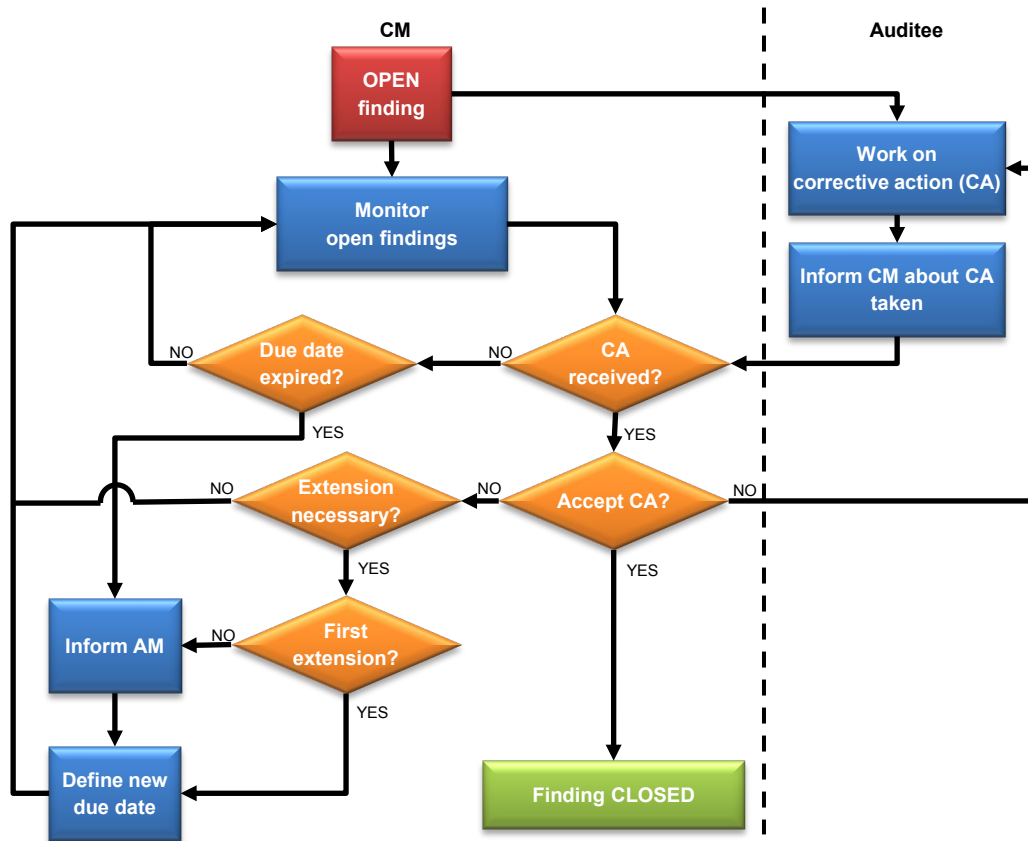
Why? – The alternator is not functioning.

Why? – The alternator belt has broken.

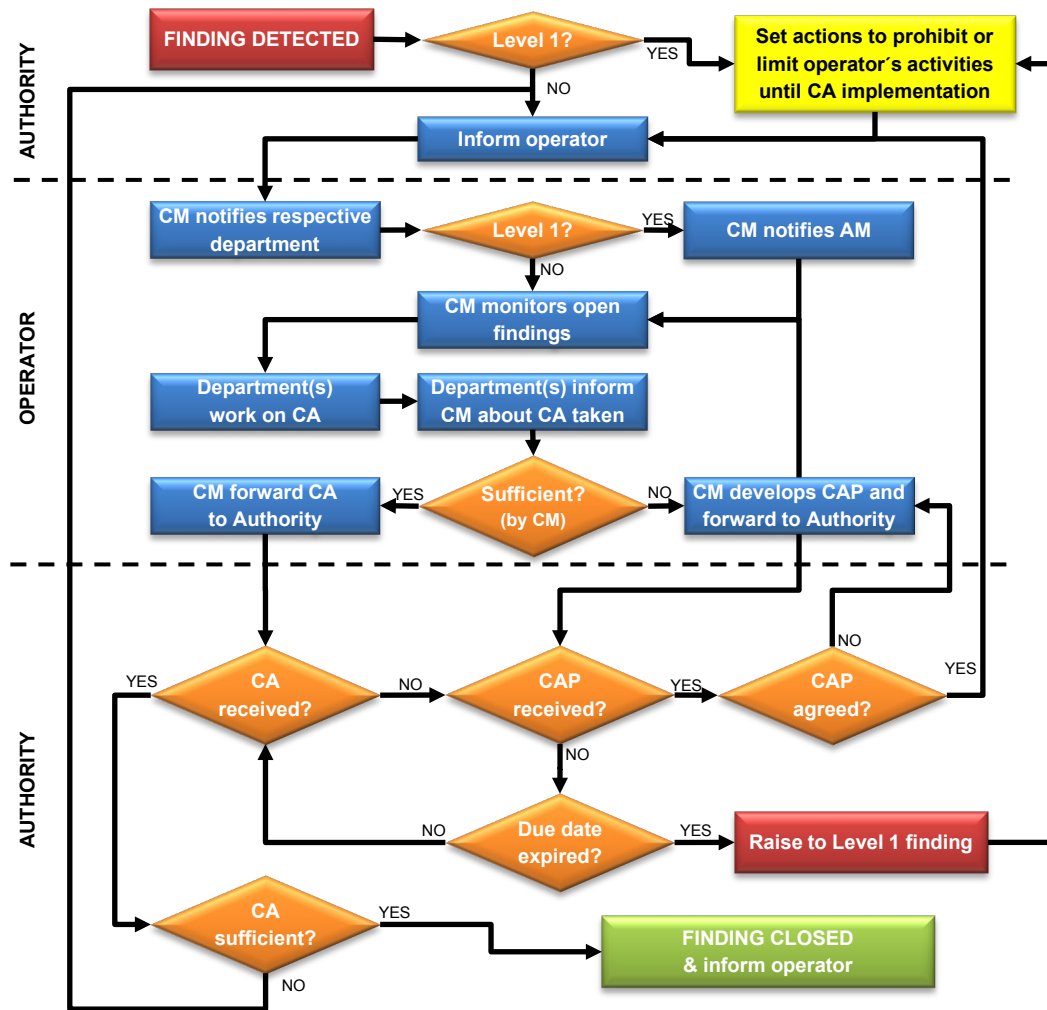
Why? – The alternator belt was well beyond its useful service life and not replaced.

Why? – The aircraft was not maintained according to the recommended service schedule.

CA – Internal Audits/Inspections



CA – Finding detected by Authority



Management Review (Management Evaluation)

A management review is a **comprehensive, systematic documented review of the highest level of management** regarding the compliance system, operating policies and procedures to:

- **evaluate the overall effectiveness** of the organization
- **the achievement of stated objectives;**
- **the effectiveness of the Safety & Compliance Management System;** and
- **the operational policies and procedures.**

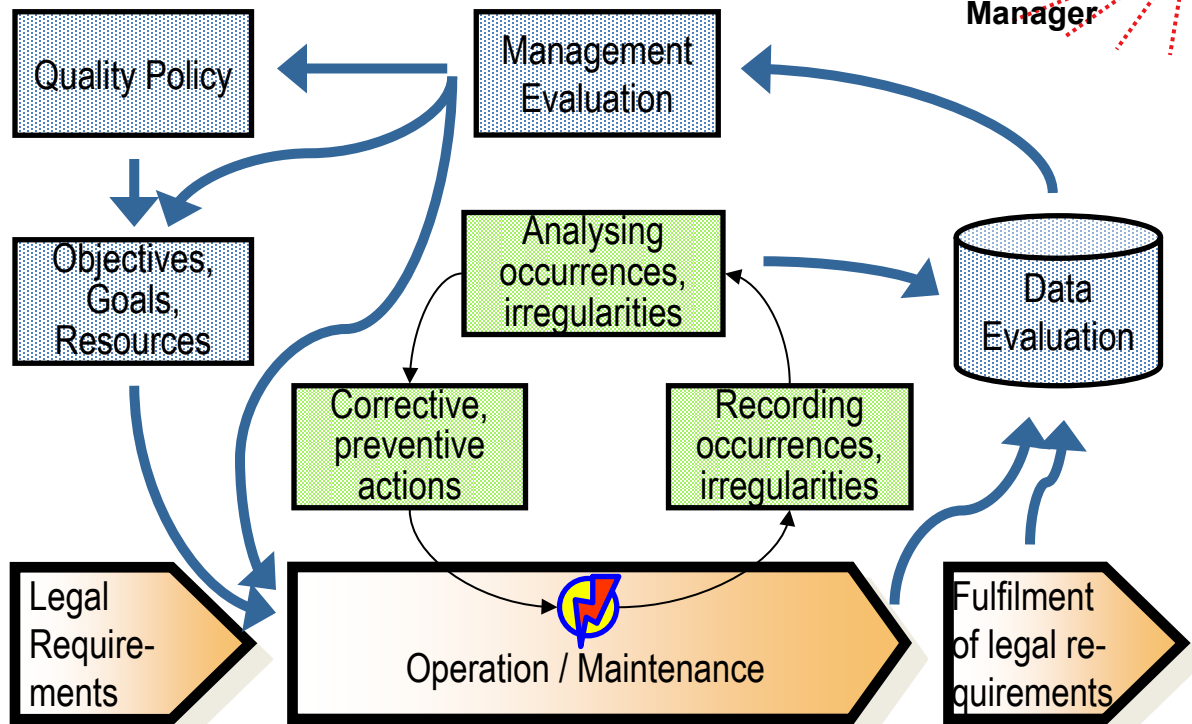
By means of these evaluations **negative trends** are brought to the attention of the highest level of management for **safety awareness purposes**.

Management Review (Management Evaluation)

Should discuss and review:

- **all findings** of audits, inspections and the competent authority detected during the preceding audit period, including:
 - the **status of corrective actions**,
 - the **cooperation of the postholders** during the corrective action implementation phase,
 - the **effectiveness** of corrective action taken, and
 - all other **actions performed by the CM** which had an impact on the compliance monitoring system (e.g. external audits, line flight observations, etc.);
- the **report from the Safety Manager** on the organization's safety performance including all safety relevant occurrences and reports; and
- the **safety policy**.

Management Evaluation



Occurrences, incidents, accidents, non-conformities, non-compliances, irregularities

Management Review (Management Evaluation)

If the management review shows any **shortcomings**, it is the **responsibility of the AM to take appropriate counter measures** to ensure the re-establishment of the overall effectiveness of the company's management organization as soon as possible.

The management review is therefore the **process enabling the AM to detect any shortcomings** regarding the overall effectiveness of the management organization.

A **written document** should be created and signed by all persons who attended the management review.

Prerequisites for applicable IT Tools and Case Management System for CAAs

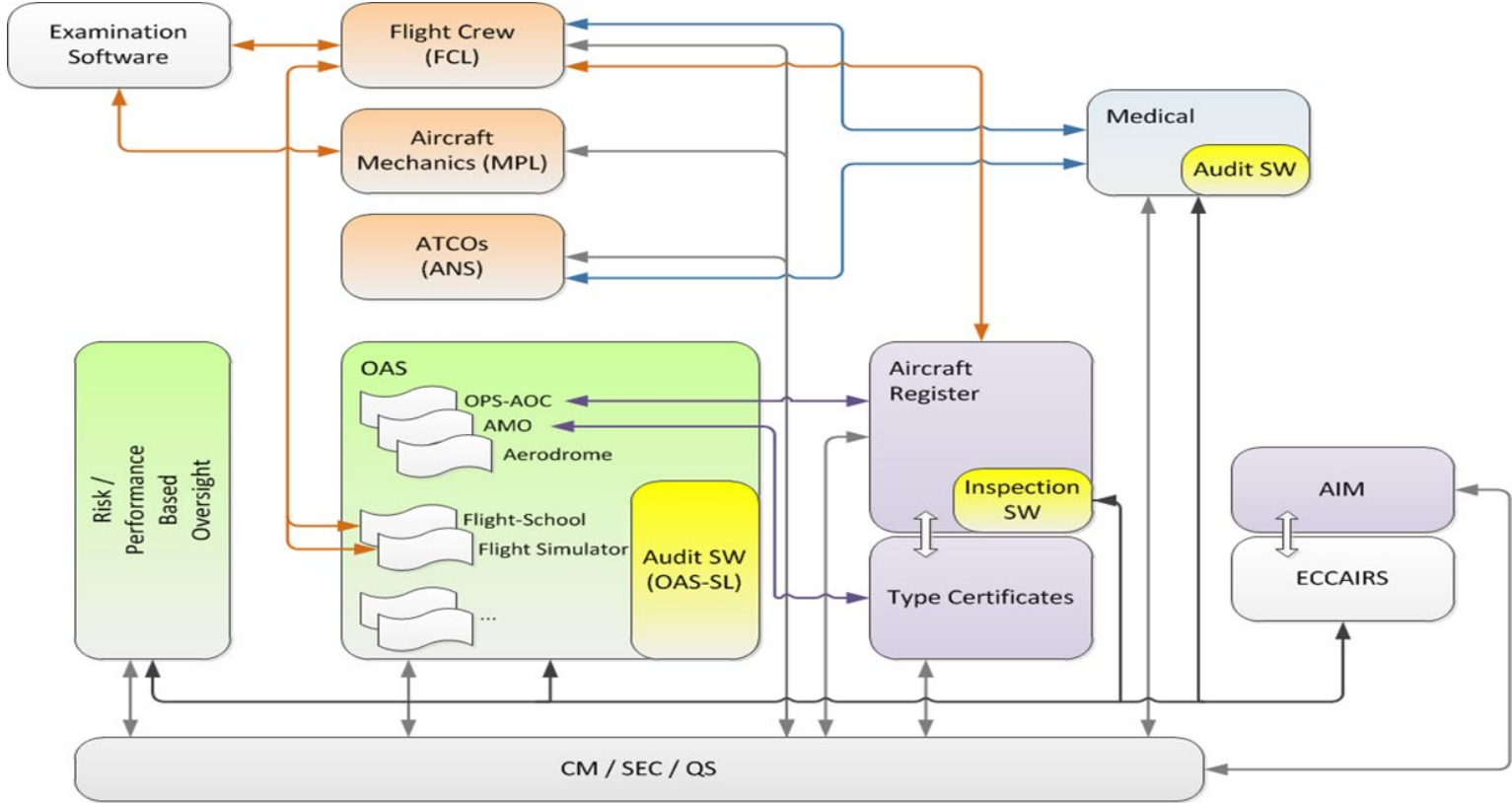
GDPR DATA PROTECTION LAW

The General Data Protection Regulation 2016/679 is a regulation in EU law on data protection and privacy in the European Union and the European Economic Area. It also addresses the transfer of personal data outside the EU and EEA areas.



- Data Protection
- No Personal data via E – Mail
- Protected storage of data (organisations and personal data)
- Encrypt communication between authorities and public
- Encrypt communication between organisations and third parties, if this communication contains personal data

Integration



CASE MANAGEMENT

- Checklist templates
- Links to surveillance activities
- Links to EMPIC objects
- Participants
- Clearance history
- Document folders

Case Ref. 45-WEE-56 Start: 12/01/17 Status: in progress

Gate 1 > Gate 2 > Gate 3 > Gate 4 > Gate 5

Header Info

Certificate Ref.	NAA.AOC.0012	Service Provider	Air Giants
Application Date	05/01/17	Address	Nürnberg
Application Type	New aircraft, new A/C type	Accountable	Roger Whitehead

Team, Setup

PM	H. Peterson	Status	in progress
AWI	G. Smith	Project Start	12/01/17
FOI	P. John	Expected End	11/03/17
		Fees	15.000 €

Gate 1 PM H. Peterson Approved 21/01/17

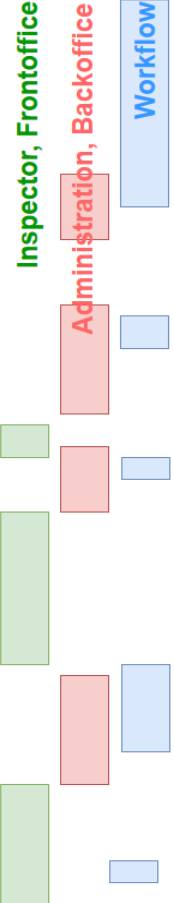
Gate 2 AWI G. Smith Approved 01/02/17

<input checked="" type="checkbox"/>	Task A	PM H. Peterson	22/01/17
<input checked="" type="checkbox"/>	Task B	PM H. Peterson	24/01/17
<input checked="" type="checkbox"/>	Task C	PM H. Peterson	26/01/17
<input checked="" type="checkbox"/>	Task C.1	FOI P. John	_____
<input checked="" type="checkbox"/>	Task C.2	FOI P. John	_____

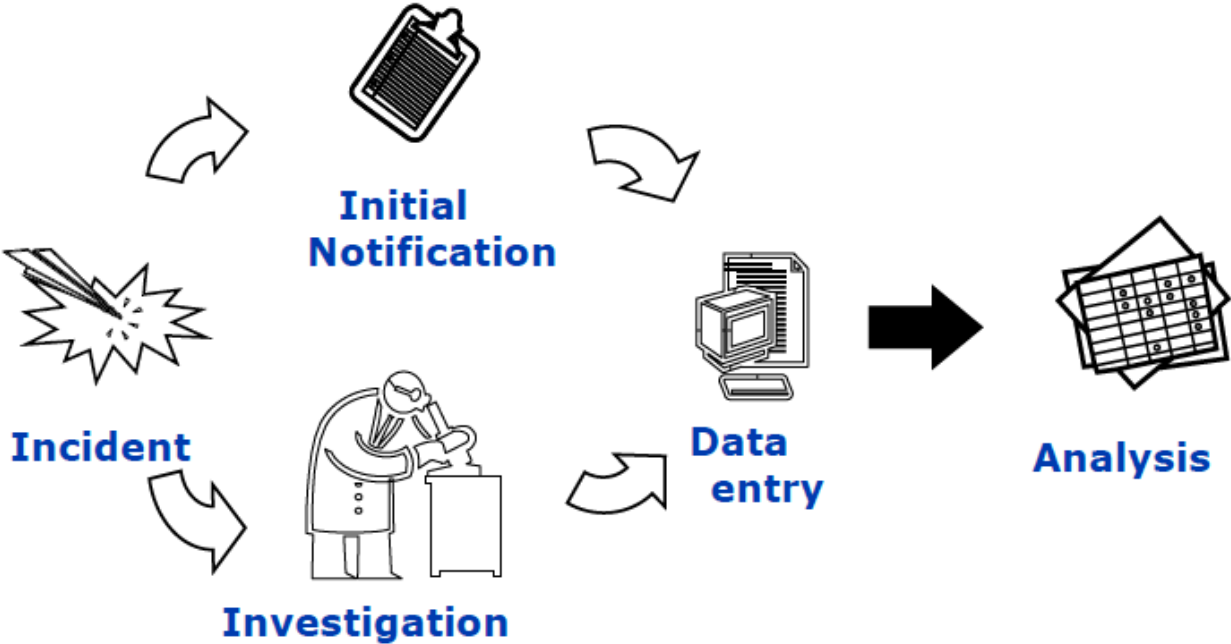
Interim Payment

Gate 3 AWI Approved

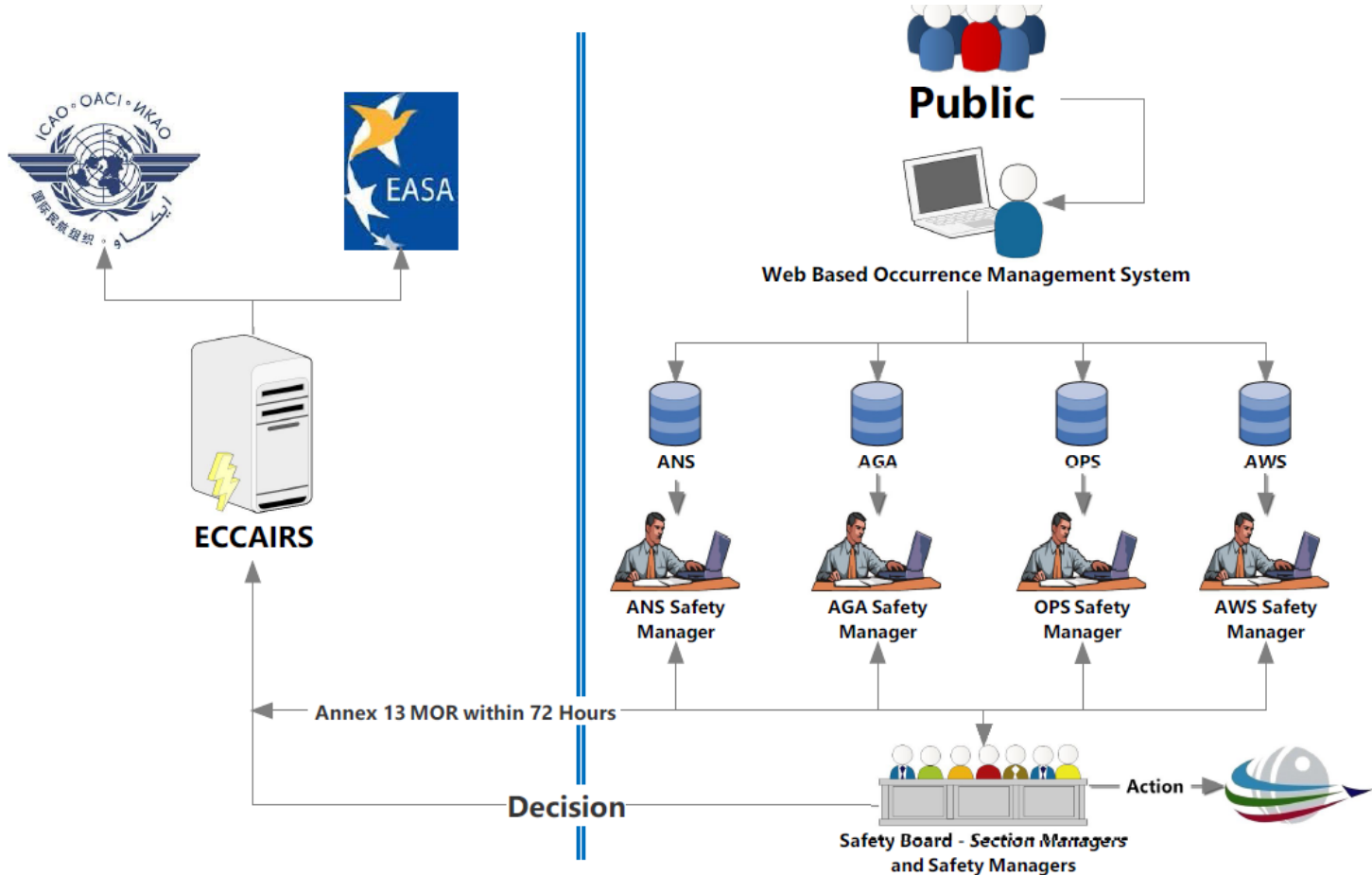
<input checked="" type="checkbox"/>	Task A	PM H. Peterson	03/02/17
<input checked="" type="checkbox"/>	Task B	PM H. Peterson	03/02/17
<input type="checkbox"/>	Task C	PM _____	_____
<input type="checkbox"/>	Check Register	_____	_____
<input type="checkbox"/>	Task C.2	_____	_____



Example Occurrence Management SSP (NAA/CAA Level)



Quality Management System Process



Performance Based Oversight versus Risk Based Oversight

Performance-based Oversight

EASA explains the relationship between Performance-based Oversight (PBO) and Risk-based Oversight (RBO) as:

The concept of "performance" conveys the idea of tangibly measuring the health of the system under scrutiny and ultimately assessing its overall performance. Performance indicators, as a means to measure, may specifically help to either identify risks within that system or measure safety risks or monitoring actions mitigating these risks. This means that a PBO can also support the identification of areas of greater risk and serve the risk assessment and mitigation exercise. This is where PBO meets RBO. [\[1\]](#)

Performance Based Regulation → History

History →



EUROPEAN AVIATION SAFETY AGENCY
AGENCE EUROPÉENNE DE LA SÉCURITÉ AÉRIENNE
EUROPÄISCHE AGENTUR FÜR FLUGSICHERHEIT



10TH ANNIVERSARY

Performance Based Regulation

Jules Kneepkens
EASA Rulemaking Director

EASA Safety Conference
10 October 2012

Your safety is our mission.
easa.europa.eu

Definition of (safety) regulation

- A regulation is a legal provision that:
 - creates, limits, or constrains a right,
 - creates or limits a duty,
 - or allocates a responsibility.

- Aviation safety regulations can also be referred to as :
 - “safety risk controls used by the regulator”

Performance based rules – how did we get there?

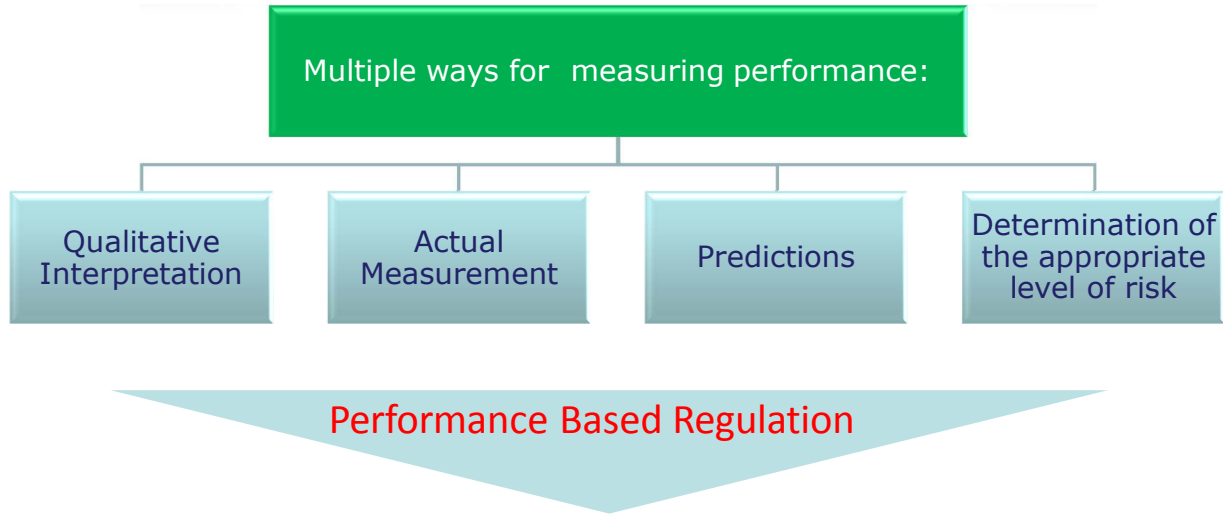
The complexity of the aviation system

New demand on regulators

- *"Value for money"*
- *De-regulation*
- *New public management*

International aviation safety standards

Measuring performance



“information costs” both for the regulator
and regulated entities

Equity and Fairness in performance schemes

- Stakeholder concerns may arise from :
 - the possibility of using a variety of means of compliance,
 - different “standards” being applied for accepting alternative means of compliance
 - different approach & methods to define and measure safety performance
 - more discretion provided to authorities for applying enforcement actions

When Implementing Performance schemes

- Proper change management is needed, considering all trade-offs in terms of :
 - Efficiency (cost/benefit)
 - Effectiveness (to mitigate safety risks / achieve the safety objectives),
 - Equity and fairness
 - Clarity and transparency
 - Maturity of management systems (of regulators and regulated persons)



Prerequisites for performance based oversight



- Commitment and Process Design including development of tailored SPIs 😊
- Continues data collection and analysis of data (Oversight)
- SMS is fully implemented 😊
- Established Occurrence Management System 😊
- Cooperation with the aviation Industry / Information Exchange
- Working Safety & Risk Management (SRM) 😊
- Implementation of suitable digital tools for data Management



Performance Based Oversight

Prerequisites for suitable digital tools



The appeal of the performance-based oversight approach is as much about introducing a new regime that overcomes problems of overly rigid rules and inflexible enforcement as it is about regulating for results.



SPIs, SPTs, and working SMS.....

used as nucleus for the development of suitable digital tools

- **SPI / Safety Performance Indicator**

Data based Safety Parameter used for monitoring and assessing Performance

- **SPT / Safety Performance Target** is a planned or intended objective for Safety Performance Indicators over a given period

- **SMS / Safety Management System** is a systemic approach for managing safety including safety performance management

NOTE: Outputs / Measurements based on SPIs or SPTs are considered as a TRIGGER
Root Cause Analysis is part of SMS

Leading Indicators and Importance of Individual Indicators for PB-RBO

Leading Indicators, applicable for all operators:

- General Assessment of Safety = Fatal Incidents Accidents
- Identifying (K) Areas incl. Root Cause Analysis
- Measuring of Effectiveness = Degree of Implementation

Individual Indicators, tailored to the operator:

- Operational Oversight, FLT, GND, Line Stations,
- Events, occurrences, implementation of SQMS
- Evidence based Training (i.e. LOFT, CFIT, manual flying, upset recovery)

Performance Indicators

Example Areas

List of Key Performance Indicators



SAFETY

- 1 Fatality
- 2 Reportable Dangerous Occurrence
- 3 Reportable Occupational Illness/ Disease
- 4 Reportable Serious Injury
- 5 Near Miss
- 6 First Aid Injury
- 7 Equipment Property Damage
- 8 Lost Time Injury
- 9 Medical Treatment Case
- 10 Restricted Workday Case
- 11 Number of Reported Issues
- 12 Bird Strike

SAFETY

13

Operational Delay

14

Cancelled Operation

15

Customer Complains

16

Percentage of Flights Delayed > 15 minutes

17

Average Minutes Delay

18

Percentage of Flights Delayed Due to Technical / Commercial Reasons

ENVIRONMENTAL

1

Spills / Releases / Discharges to Land

2

Spills / Releases / Discharges to Water, including Groundwater

3

Releases / Discharges to Atmosphere

4

Vegetation Removal / Harm

5

Harm to Animal Species

6

Damage to Cultural Site

7

Environmental Noise / Vibration

8

Other

FINANCIAL



Operating Margin



Revenues



Expenses



Revenue Per Available Seat

FLIGHT OPS

1

Number of Flights

2

Number of PAX

3

Available Flying Time

4

Aircraft Utilization

5

Average Turnaround Time

6

Average Block Hours per Day

7

Number Lost Baggage Incidents

8

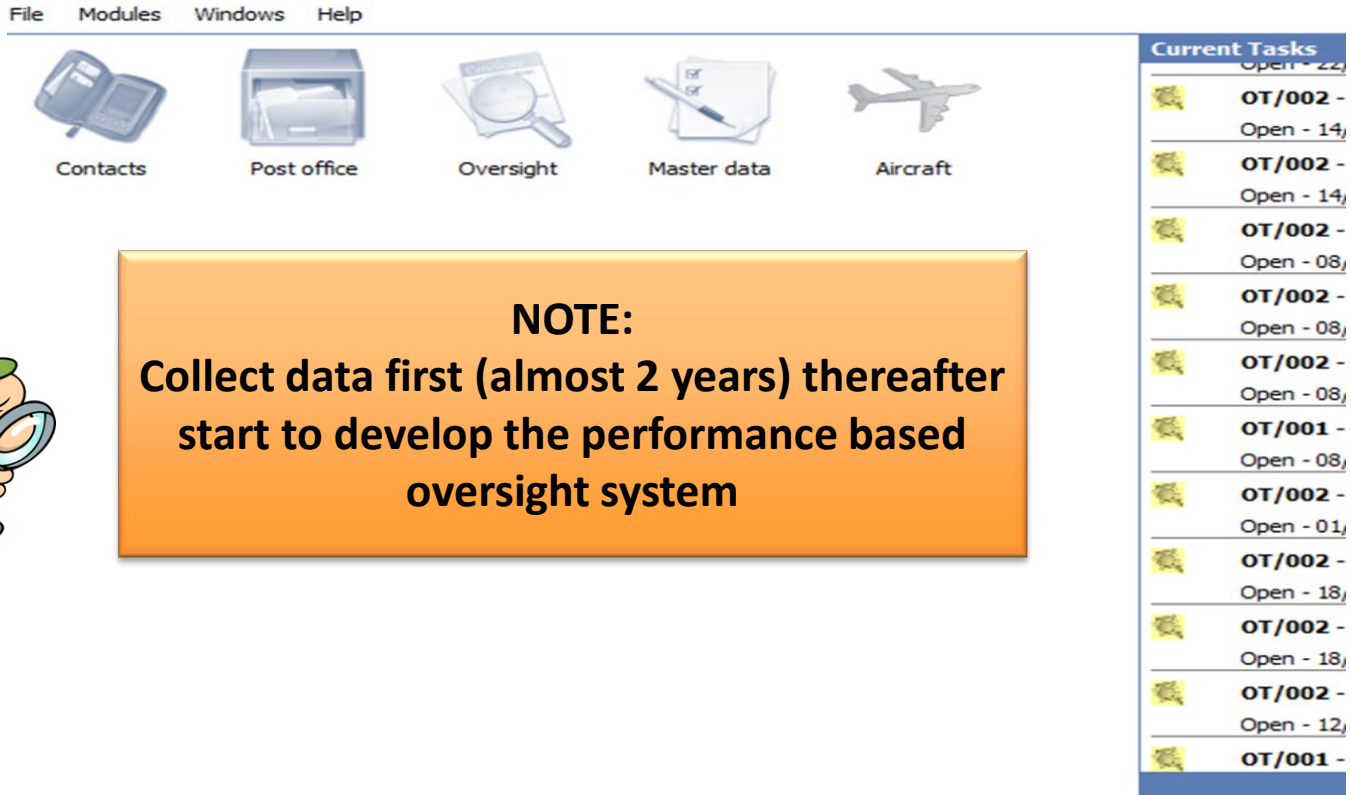
Lost Time Injury

9

Medical Treatment Case

Introduction to Oversight Tool

Front End = Data Collection



File Modules Windows Help

Contacts Post office Oversight Master data Aircraft

Current Tasks

- Open - 22
- OT/002 - Open - 14
- OT/002 - Open - 14
- OT/002 - Open - 08
- OT/002 - Open - 08
- OT/002 - Open - 08
- OT/002 - Open - 08
- OT/001 - Open - 08
- OT/002 - Open - 01
- OT/002 - Open - 18
- OT/002 - Open - 18
- OT/002 - Open - 12
- OT/001 -



NOTE:
Collect data first (almost 2 years) thereafter start to develop the performance based oversight system

Data Base

File Module Reports Help

Save Discard Reload Cluster-View Show/hide intermediate level

Interval Reports

1/01/2015 - 31/12/2015

OT/002: Airways - OPS1

12/02/2013 - 31/12/2013

OT/002: Airways - OPS1

01/01/2014 - 31/12/2014

OT/002: Airways - OPS1

1/01/2015 - 31/12/2015

New Delete

Audits Reports

08/01/2015
E-Enroute Inspection and Fl...
701-1/133-15 ✓

11/01/2015
FL-Operator's Facilities at Lin...
701-1/131-15 ⚠

11/01/2015
R-Ramp ✓
701-1/132-15

13/01/2015
E-Enroute Inspection and Fl... ✓
701-1/134-15

15/02/2015
C-Aircraft Cabin and cabin cr... ✓
701-1/136-15

15/02/2015
C-Aircraft Cabin and cabin cr... ⚠
701-1/138-15

15/02/2015
E-Enroute Inspection and Fl... ✓
701-1/137-15

15/02/2015
E-Enroute Inspection and Fl... ✓
701-1/135-15

Interval

Approval OT/002

From 01/01/2015 Until 31/12/2015 Subject Note

Type Main interval Business Case

Approval Reports

Approval No OT/002 Typ

Type of Business OPS1

Details Approval Checklist AOC

Application Date 12/02/2013 Closing Date

Idle from Idle until

Postholder AM
PHFO

Initial date of issue 01/01/1990 Date of Revision 05/12/2013

Current File# OPS- -A-080-13 No. of Revision

Completion

Location

Number of Employees 12000

OPS Contact

Team Member & Role

AAA/AOC Issuer
W1/OPS Issuer

Organisation

Name Airways

Contact Details

Street Address

ZIP Code 1 City

Phone

Fax

Email

CEO

Approval Schedule

Approval Schedule

Aircraft Registration

- B777-300ER
- A330-202
- A330-202
- A330-202
- A330-243E

New Delete

Back End = SRM based on ISPI and Audit Data

Risk assessments

Create new assessment
 Print report
 Delete last assessment

Current assessment from 27/04/2014: **medium**

The audit / inspection interval is 12 months.

NO CURRENT DATA – DUMMY DEMO SHOT ONLY

No	Risk parameter	Risk assessment	Risk classification	Scores	Trend
1	Safety-, Risk- und Quality Management System	A well structured, documented quality system is implemented within the operation. The management and the postholder have clear oversight on the goals of the quality system. Risks are identified and processed	low	0	→
2	Management Structure	One named person executes two leading functions within the operation.	mean	1	→
3	Change of management personell	One leading function was changed within the last 12 months.	mean	1	↑
4	Full- /Part-Time employment of management perso...	All persons in leading functions are employed at other companies as well.	high	3	→
5	Size of fleet	Each fleet consists of only one aircraft.	high	3	→
6	Operation of different aircraft types	3 to 5 aircraft types are operated.	medium	2	→
7	Special operations	Special airports or countries are operated. Cargo with special approvals is transported. Crew training is not adequately performed.	medium	2	↓
8	Infrastructure	Infrastructure and equipment is adequate for the size of the company. Equipment is ready for use and documents are available. No safety concerns.	low	0	→
9	Training	The described training is performed and documented. Documentation is available. Training is adequate and efficient.	low	0	→
10	Duty and rest times	The company has a system for tracking on duty and off duty times, which is adequate. Control for crew members and dispatch is automatically performed.	low	0	→
11	Cooperation with the authority	The company refuses scheduled dates. Postholder are not available. Documentation is only accessible on demand. Corrective actions are not executed on time.	medium	2	→
12	Knowledge of the company	AOC was issued in the last 12 to 24 months. Number of times changed within the last 12 months: within the last 24 months: 3; new size of fleet	medium	2	→

Assessment history

Date	Risk assesment	%	Trend	Report
27/04/2014	medium	51%	→	
20/02/2014	medium	51%	→	
02/02/2014	medium	51%	↓	
26/02/2013	medium	59%		

[Overview](#) |
 [Auditplanning](#) |
 [List of questions-Planning](#) |
 [List of questions-Execution](#) |
 [Findings](#) |
 [Closure](#) |
 [Risk assessment](#)

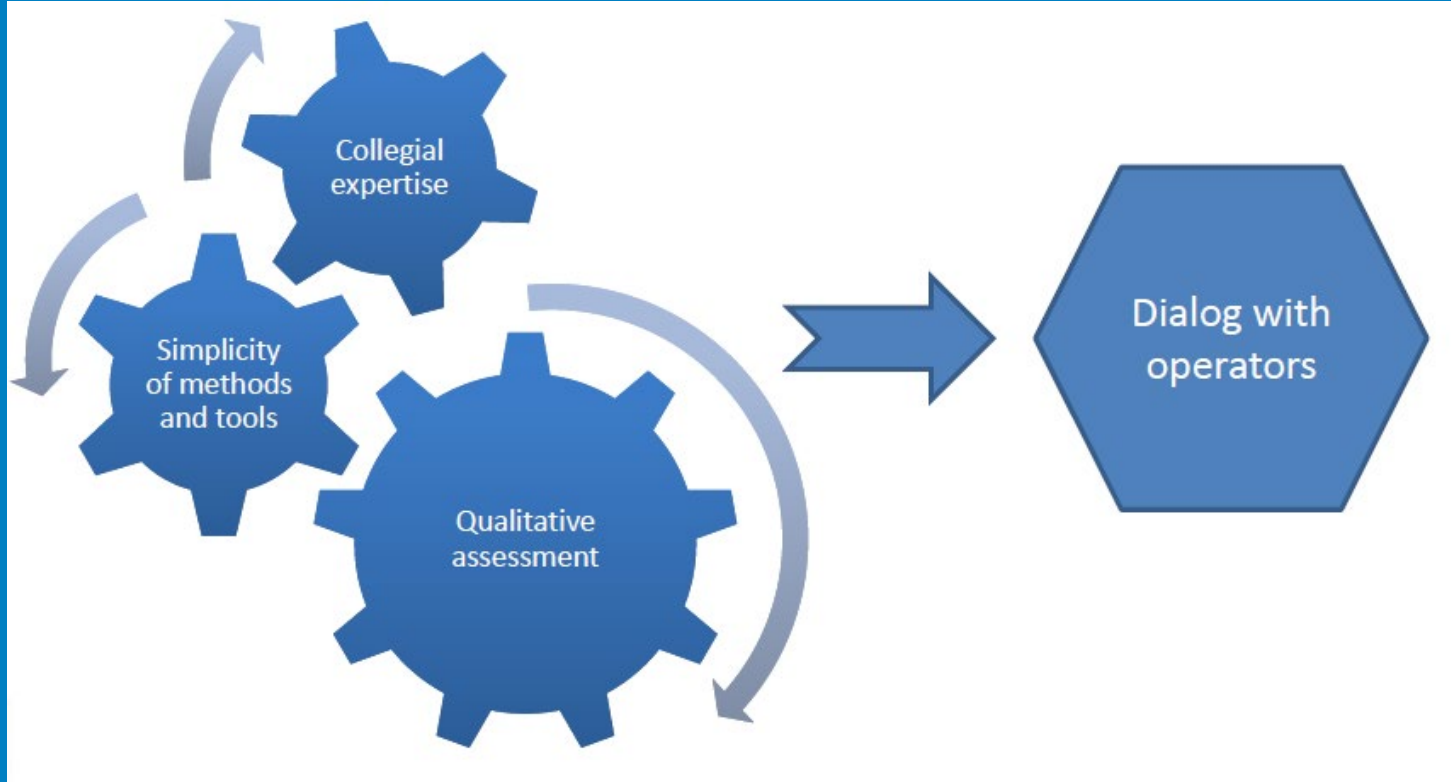
Prerequisites for Performance Based Oversight



- ✓ Climate of trust between CAA and Aviation Industry
- ✓ Monitoring Compliance with legal framework
- ✓ Using SMS as a Tool to grant derogations and exemptions
- ✓ Learning from the aviation industry
- ✓ Crosschecking and flexible oversight methods in force
- ✓ Continues Risk mitigation via data collection and cooperation
- ✓ Communication



Risk Based Oversight Principles



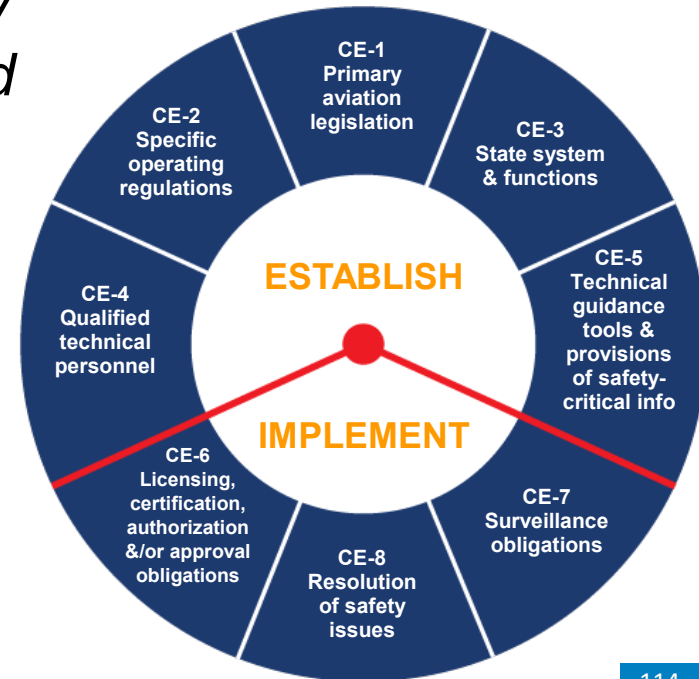
The state oversight system

Safety Oversight: *“A function performed by a State to ensure that individuals and organizations performing an aviation activity comply with safety-related national laws and regulations.”*

[Annex 19 to the Chicago Convention — Safety Management (Second edition, July 2016)]

The State Safety Oversight (SSO) system CEs constitute the foundation of an SSP (State Safety Programme)

Essential components (CEs) of a Safety Oversight System



$$\text{PBE} = \text{PBR} + \text{RBO}$$

PERFORMANCE BASED ENVIRONMENT

PERFORMANCE
BASED **REGULATIONS**

RISK BASED
OVERSIGHT



CE-1 CE-2 CE-3

CE-4
CE-5

CE-6 CE-7 CE-8



What is RBO? – Definitions

Oversight:

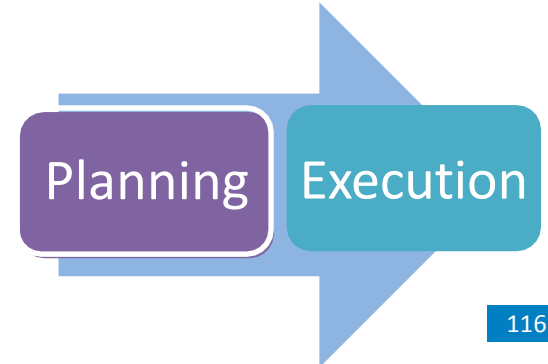
The function by means of which a competent authority ensures that the applicable requirements are met by regulated entities.

Surveillance: The State activities through which the State proactively verifies through inspections and audits that aviation licence, certificate, authorization or approval holders continue to meet the established requirements and function at the level of competency and safety required by the State.

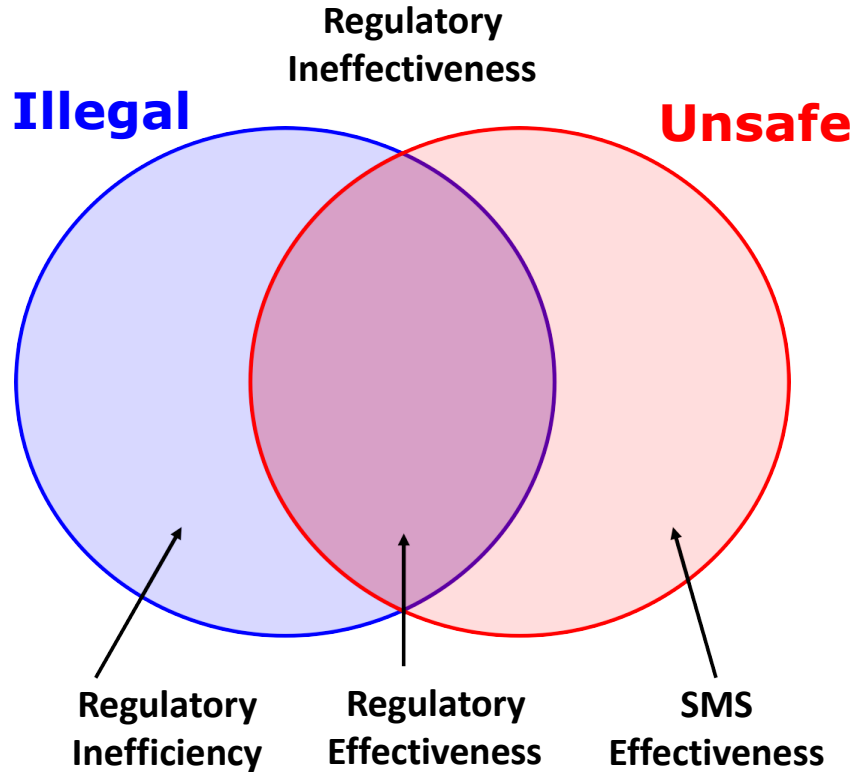
(ICAO Annex 19, Second Edition, July 2016)

Risk Based Oversight:

A way of performing oversight, where **planning** is driven by the combination of risk profile and safety performance; and **execution** focuses on the management of risks, besides ensuring compliance.



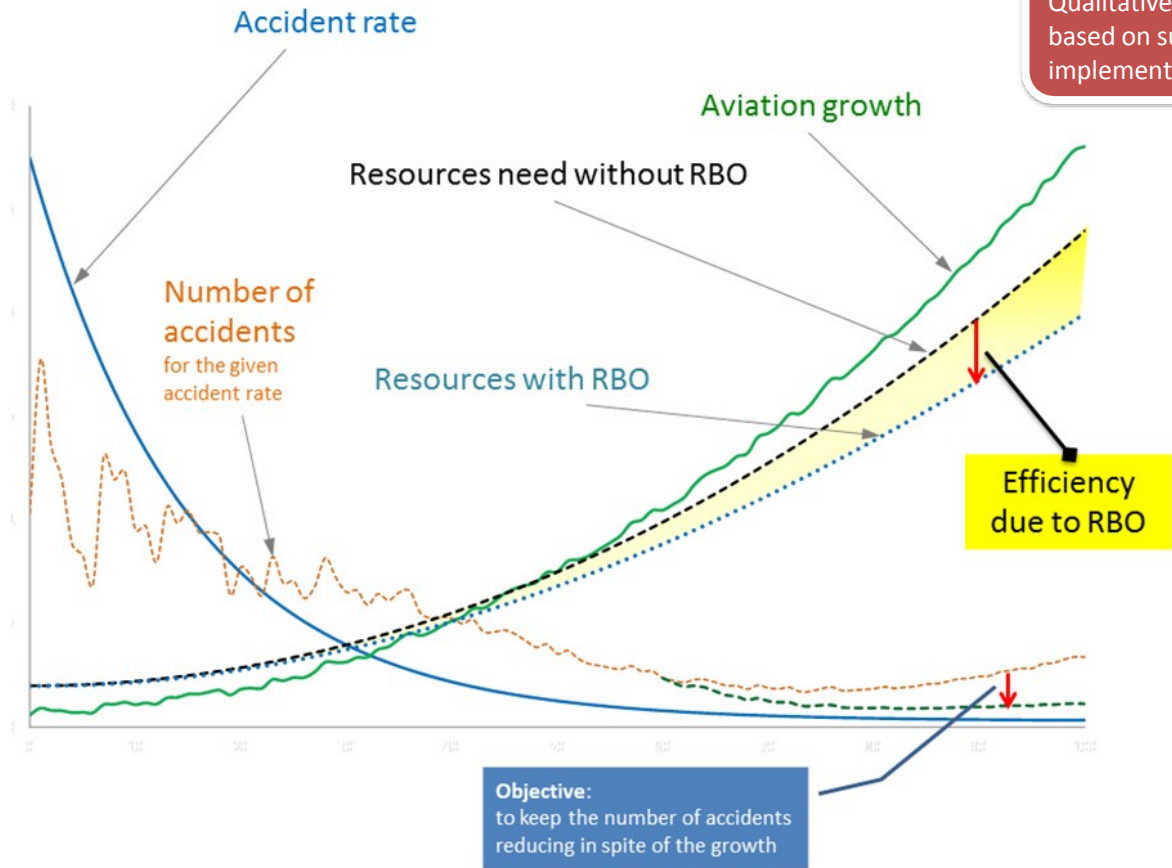
Why is RBO interesting?



- Data driven
- Targeted use of resources
- Focus on safety
- Positive effect of prescriptive requirements is maintained

Why is RBO interesting?

DISCLAIMER
Qualitative assumption based on successful implementation



Types of Risk

Business risk	Any event or issue that could occur and adversely impact the achievement of the Agency's political, strategic and operational objective. Lost opportunities are also considered as risks.
Hazard	A condition or an object with the potential to cause or contribute to an aircraft incident or accident.
Safety risk	The predicted probability and severity of the consequences or outcomes of a hazard.
Operational risk	The safety risk connected with the performance of operations

RISK BASED OVERSIGHT: a way of performing oversight allowing the competent authority to:

- prioritise and plan its activities based on compliance, risk profiling and assessment of the safety performance; and
- verify compliance with a focus on management of operational risks.

Risk profile and safety performance

Risk Profile

The elements of risk that are inherent to the nature and the operations of the regulated entity



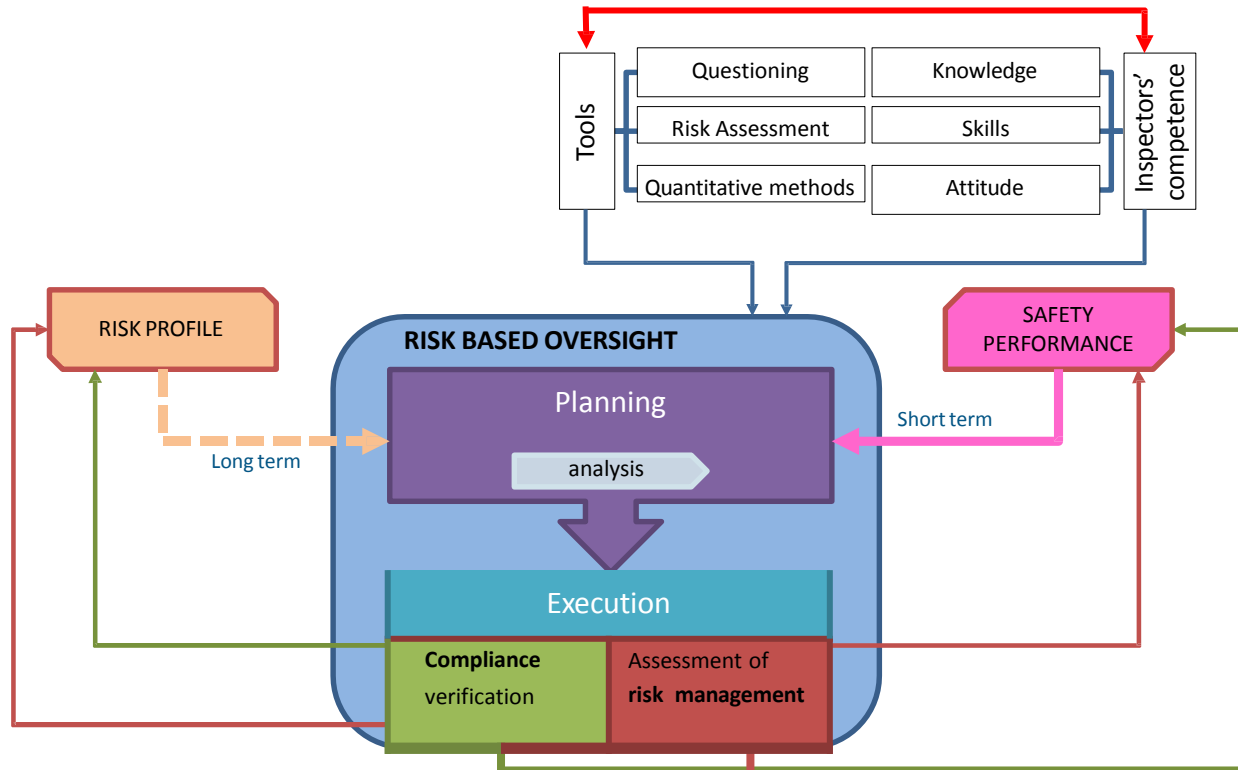
Risk profile and safety performance

Safety Performance

The demonstration of how effectively can a regulated entity mitigate its risks



Conceptual RBO Model



RBO Enablers

Management of
safety
information

Information
sharing

Accountabilities,
responsibilities
and enforcement

Culture

Organisational
requirements

Mature safety
management

Inspector
Competence
and
qualifications

1

Oversight planning and determination of oversight cycle for each organisation should take into consideration the risk profile and the assessment of the safety performance. When the risk profile relies on expert judgment, the decision making should be made by consensus by a team of experts.

2

For each organisation, RBO parameters should be continuously monitored at an appropriate frequency in order to identify any trend and to review the oversight programme, its cycle and the safety objectives. The competent authority should continuously follow-up and improve the overall RBO system.

3

The ICAO state safety programme (SSP) should be established and used as a background framework for RBO and the competent authority should have a functioning management system, as required by the rules.

4

The state oversight system should be mature enough before it can be complemented by RBO. This oversight approach should be linked to the objectives of the SSP and of the management system of the competent authority. EASp actions should also be taken in consideration.

5

The management system of the competent authority should capture the different risk profiles of the regulated entities according to a model. When determination of risk profile relies on expert judgment, decision making should be made by consensus by a team of experts.

6

RBO should be progressively deployed and extension of RBO to additional domains should be consistent and appropriate. Initial introduction of RBO could be facilitated by a dedicated team of “champions’ inspectors.

7

A system in place for the collection, analysis, and exchange of safety data at the level of State and regulated entity is a prerequisite for RBO, as well as safety management principles and a just culture environment. Exchange of information on safety risks between competent authority and regulated entities should be established. Development of an integrated risk picture in and across different domains should be done in partnership with involved stakeholders.

8

Competent Authorities should develop arrangements for cooperation on oversight, exchange of collected safety information, sharing of RBO experience, feedback on experience with the SSP, etc.

9

Initial and continuous training should be given to inspectors implementing RBO, to cover:

- development of proper culture when interacting with industry
- use of expert judgment, specially when safety performance and “gut feeling” are blended
- use of RBO-specific tools available at the competent authority.
- Support and coaching should be available during the initial phase of RBO deployment.

Profile & Performance

Ratings & Limitations

Level of maintenance

Number of staff

Specialized service

Maintenance sites

Scope of Approval

Intrinsic organisation risk profile

Outsourcing

Non Permanent staff & Part-66 licensed Engineers

Use of the approval & Other approval held

Number of years using the EASA approval

Fabrication of parts

Organisation Activity

Organisation Performance Risk Profile



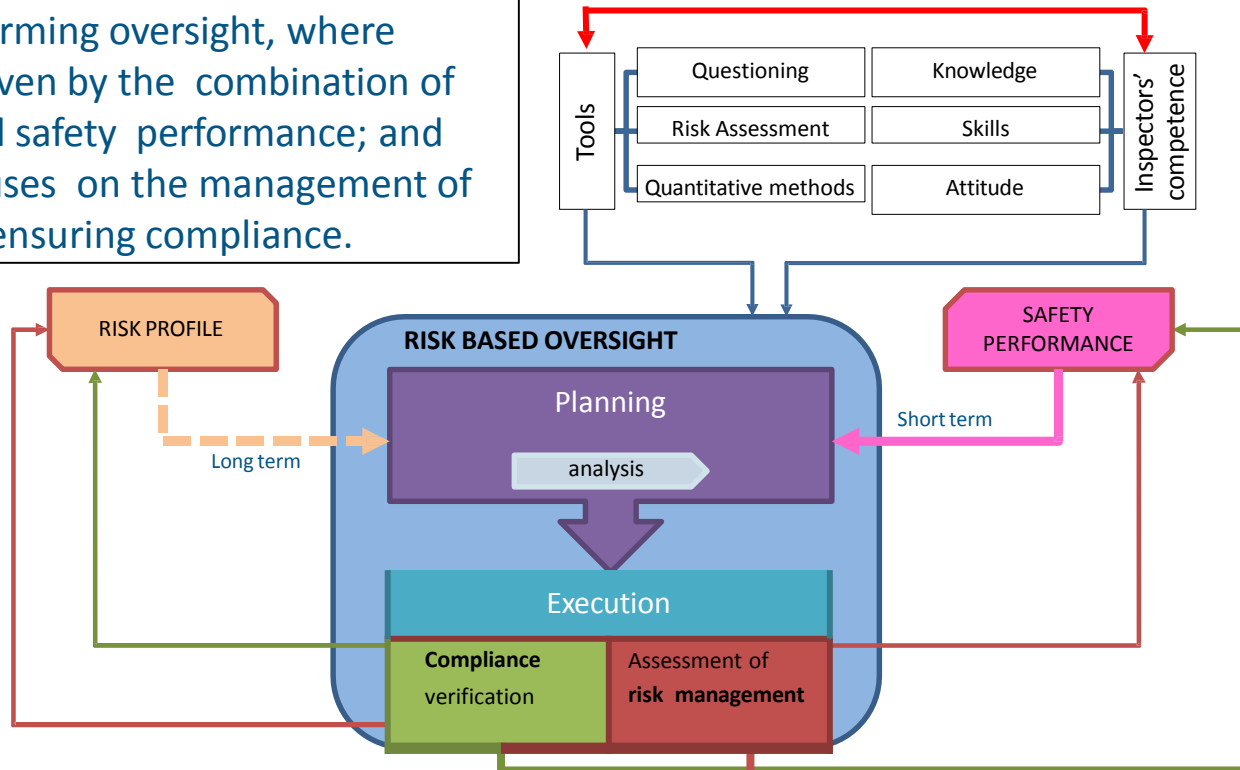
From PBO to RBO



To take home

Risk Based Oversight:

A way of performing oversight, where **planning** is driven by the combination of risk profile and safety performance; and **execution** focuses on the management of risks, besides ensuring compliance.



Implementation Timeline

- PB – RB oversight setup must be process orientated and will need the commitment of all stakeholders involved (CAA, Operators..)
- Implementation of digital oversight tools in order to use them for PB Oversight will take time (2-3 years)
- The proper selection of tools and providers is VERY important. It will be difficult to change the provider later on without loosing data as required for risk analysis

Performance and Risk Based Oversight



- ✓ Will never work without an established Safety Culture
- ✓ Needs a clear Safety Leadership within the organisation
- ✓ Needs fully implemented QM,SMS
- ✓ Needs competent inspectors and continues training of all personnel involved
- ✓ Needs clear established procedures, rules and SOP,s
- ✓ Needs digital tools, effective data monitoring, evaluation and risk-based occurrence management
- ✓ Need to adhere to international established SARPs, especially if the aviation industry is asking for exemptions and derogations

Tools for Risk Monitoring

Oversight (Test)

File Module Reports Help

Commit Discard Reload

OPS1 01.01.2012 -

Type of Business OPS1 Valid from 01/Jan/2012 Valid until

Algorithm

```

DECLARE
FUNCTION getSumme
RETURN NUMBER
AS
summe NUMBER;
anzahl NUMBER;
    
```

Sort/ID	Name	Color	Value	Sort/ID	Name	From	Until	Text	Interval
0	low	0		1	high	0	50	The audit / inspection inter...	6
1	mean	1		2	medium	50	65	The audit / inspection inter...	12
2	medium	2		3	mean	65	75	The risk is rated mean.The ...	24
3	high	3		4	low	75	100	The risk is rated low.The ou...	24

Sort/ID	Name	Valid from	Valid until	Algorithm	Note
1	Safety-, Risk- und Quality Managemen...	01.01.2...		DECLARE FUNCTION getRisk1 RETURN NUMBER AS	a... Ermittlung auf Besi...
2	Management Structure	01.01.2...		DECLARE FUNCTION getRisk2 RETURN NUMBER AS	... Ermittlung der alt...
3	Change of management personell	01.01.2...		DECLARE FUNCTION getRisk3 RETURN NUMBER AS	a... Ermittlung der alt...
4	Full- /Part-Time employment of manag...	01.01.2...		DECLARE FUNCTION getRisk4 RETURN NUMBER AS	... Ermittlung aller alt...
5	Size of fleet	01.01.2...		DECLARE FUNCTION getRisk5 RETURN NUMBER AS	a... Ermittlung des Ge...
6	Operation of different aircraft types	01.01.2...		DECLARE FUNCTION getRisk6 RETURN NUMBER AS	a... Ermittlung des Ge...
7	Special operations	01.01.2...		DECLARE FUNCTION getRisk7 RETURN NUMBER AS	a... Es werden die OP...

Text for risk category

Value	Text

MS Access

Conclusion RBO



- ✓ **Teamwork / cooperation and proactive, safety related approaches** are required between all stakeholders to overcome old structures
- ✓ If we try to understand each stakeholder's needs, we are able to **learn from each other** and we will develop a good safety system together
- ✓ A **well-established professional culture and a proven, open minded organisational culture in an organisation** should supersede ☹️ habits and personal goals and agendas of individuals.

Risk Assessment

Hazard Identification and Risk Assessment

Hazard generically defined 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.

Risk is the assessed potential for adverse consequences resulting from a hazard. It is the likelihood that the hazard's potential to cause harm will be realised. (ICAO Doc 9859)

Risk the combination of the overall probability, or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect. (EU Reg. 1035/2011)

Hazard Identification and Risk Assessment

- Hazards are an **inevitable part of aviation** activities.
- Common **tendency to confuse hazards with their consequences** or outcomes.
 - A consequence is an outcome that can be triggered by a hazard
 - Example: A runway excursion (overrun) is a projected consequence in relation to the hazard of a contaminated runway → By first defining the hazard clearly, one can then project the proper consequence or outcome.*
- **Hazards should be differentiated from error**, a normal and unavoidable component of human performance, which must be managed.

Hazard Identification and Risk Assessment

The SMS needs to include a **process to identify hazards** and develop **processes to identify and manage risks**.

Key elements of **Hazard Identification and Risk Assessment programs** are:

- **Proactive identification of existing and potential hazards**. This includes those hazards associated with organizational change when the organization is undergoing rapid growth, introducing new services, new equipment or new personnel
- A process to **prioritize risk management**
- A method to **track identified hazards**

Hazard Identification and Risk Assessment

Three methodologies for identifying hazards:

Reactive – Involves analysis of past outcomes or events. Hazards are identified through investigation of safety occurrences.

Proactive – 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. This involves actively seeking hazards in the existing processes.

Predictive – 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.

Hazard Identification and Risk Assessment

Reactive Safety Management is:

- **Based on Investigation** of accidents and serious incidents
- Based upon the predisposition of **waiting until something breaks**
- Triggering causes and contributory factors to risks are identified

➔ Analysis of "what happened and why?"

Hazard Identification and Risk Assessment

Pro-active Safety Management is:

- **Based on** mandatory and voluntary **reporting systems**, safety and quality **audits** and **surveys**
- Based upon the predisposition that non-conformities can be minimized by identifying safety risk within a system before it fails and that necessary actions can be taken to reduce such risks
 - **Analysis of "what happens and why?"**

Hazard Identification and Risk Assessment

Predictive Safety Management is:

- **Aggressively seeking** information from variety of sources which may be indicative of emerging safety risks
 - Based upon the predisposition that we have to **look for trouble and not to wait for it.**
- Analysis of " what can happen and why?"

Hazard Identification and Risk Assessment



Hazard Identification and Risk Assessment

- 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.
- **Important mechanism for proactive hazard identification** is a voluntary hazard/incident reporting system.

Hazard Identification and Risk Assessment

A **risk assessment matrix** is a useful tool to identify the level of risk and the levels of management approval required for any Risk Management Plan.

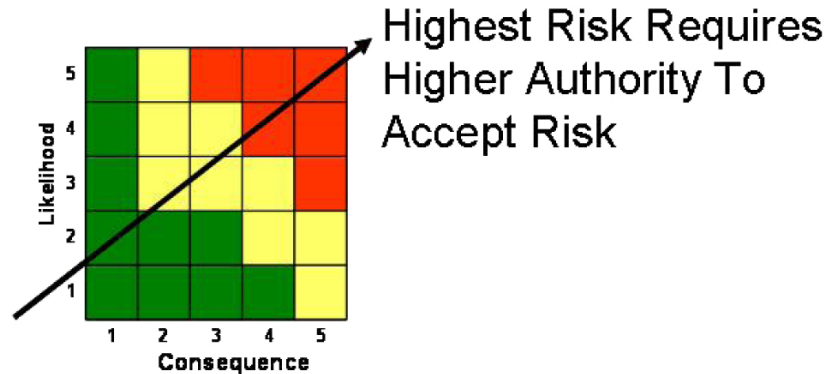
There are **various forms of this matrix**, but they all have a common objective to define the potential consequences or **severity** of the hazard versus the **probability / likelihood** of the hazard.

Hazard Identification and Risk Assessment

		PROBABILITY				
		FREQUENT	PROBABLE	OCCASIONAL	REMOTE	IMPROBABLE
SEVERITY	I - CATASTROPHIC	1	2	4	8	12
	II - CRITICAL	3	5	6	10	15
	III - MARGINAL	7	9	11	14	17
	IV - NEGLIGIBLE	13	16	18	19	20

Figure 1.2

Lowest Risk Allows
Lower Authority To
Accept Risk



Hazard Identification and Risk Assessment

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

Hazard Identification and Risk Assessment

Catastrophic:

- Equipment destroyed
- Multiple deaths

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

Hazard Identification and Risk Assessment

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

Minor:

- Nuisance
- Operating limitations
- Use of emergency procedures
- Minor incident

Hazard Identification and Risk Assessment

Negligible:

→ Few consequences

Hazard Identification and Risk Assessment

	Probability of Occurrence Definitions				
	Extremely improbable	Extremely remote	Remote	Reasonably probable	Frequent
Qualitative definition	Should virtually never occur in the whole fleet life	Unlikely to occur when considering several systems of the same type, but nevertheless has to be considered as being possible	Unlikely to occur during the total operational life of each system but may occur several times when considering several systems of the same type	May occur once during total operational life of one system	May occur once or several times during operational life
Quantitative definition	$< 10^{-9}$ per FH	10^{-7} to 10^{-9} per FH	10^{-5} to 10^{-7} per FH	10^{-3} to 10^{-5} per FH	1 to 10^{-3} per FH

Risk Tolerability Matrix

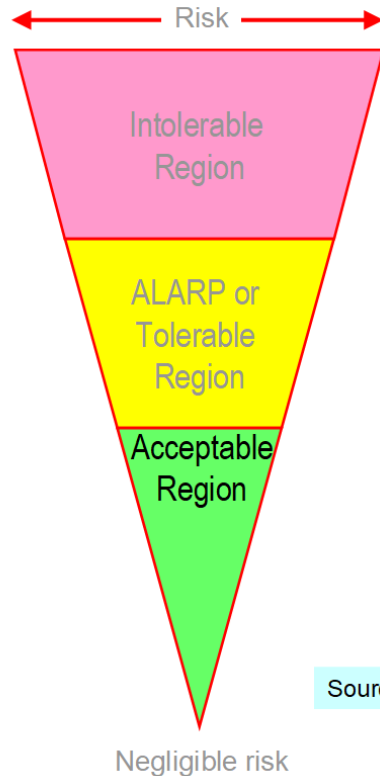
Risk index range	Description	Recommended action
5A, 5B, 5C 4A, 4B 3A	High risk	Cease or cut back operation promptly if necessary. Perform priority risk mitigation to ensure that additional or enhanced preventive controls are put in place to bring down the risk index to the moderate or low range.
5D, 5E, 4C, 4D, 4E, 3B, 3C, 3D 2A, 2B, 2C 1A	Moderate risk	Schedule performance of a safety assessment to bring down the risk index to the low range if viable.
3E, 2D, 2E, 1B, 1C, 1D, 1E	Low risk	Acceptable as is. No further risk mitigation required.

Risk Mitigation

→The goal is to **mitigate risk from an intolerable region to an acceptable region**, but at least to a tolerable region making use of the “ALARP Principle”:

Risk Mitigation

The ALARP Principle



- Risk is unacceptable at this level
- Risk cannot be justified

ALARP = As low as reasonably practicable

- Risk is undertaken only if a benefit is desired
- Tolerable only if further risk reduction is impracticable or if its cost is grossly disproportionate to the improvement gained → cost / benefit analysis
- Maintain safety assurance that risk remains at this level

Source: ICAO Safety Management Manual / Doc 9859 / §4.2

Risk Mitigation

Risk Assessment shall evaluate the most adequate strategy.

Not all possibilities have the same potential to reduce risks.

→ Evaluate for each strategy the effectiveness

Risk Mitigation

The full range of possibilities should be evaluated and for each proposed risk mitigation option, the following questions might be answered and documented:

→ **Effectiveness:**

- Will it reduce or eliminate the identified risk?
- To what extent do alternatives mitigate the risk?

→ **Cost/Benefit:**

- Do the perceived benefits of the option outweigh the costs?
- Will the potential gains be proportional to the impact of the change required?

Risk Mitigation

→ Practicality:

→ Is it doable and appropriate in terms of available technology, financial feasibility, administrative feasibility, governing legislation and regulations?

→ Challenge:

→ Can the risk mitigation measure withstand critical scrutiny from all parties involved?

→ Acceptability to each party involved:

→ How much cooperation (or resistance) from each party involved can be expected?

→ Enforceability:

→ If new rules (SOPs, etc.) are implemented, are they enforceable?

Risk Mitigation

→Durability:

- Will the measures withstand the test of time?
- Will it be of temporary benefit or will it have long-term utility?

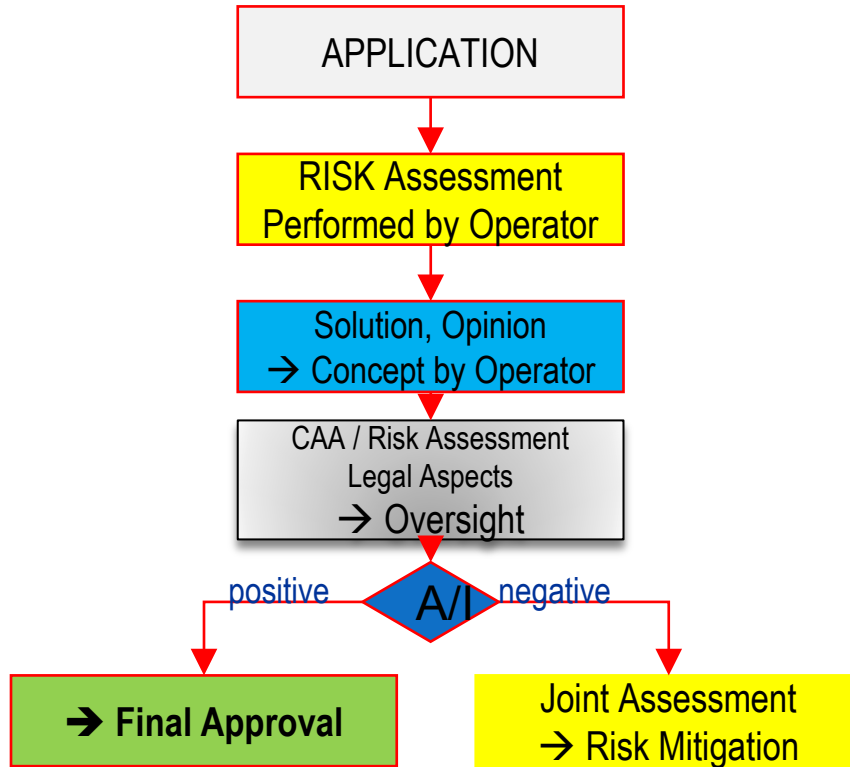
→Residual risks:

- After the risk mitigation measure is implemented, what will be the residual risks relative to the original hazard?
- What is the ability to mitigate any residual risks?

→Newly introduced Problems:

- What new problems or new risks will be introduced by the proposed change?

Example: Approval Process



Initial Approval
Final Approval

Internal Hazard & Occurrence Reporting

Internal Hazard & Occurrence Reporting

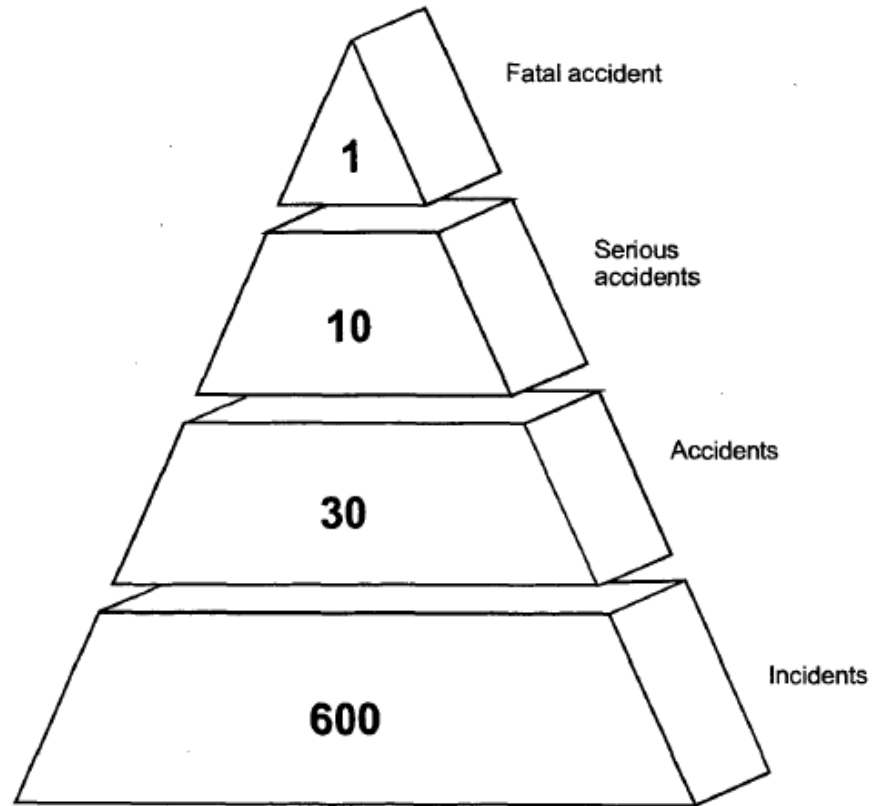
Occurrences are **unplanned safety related events**, including accidents and incidents that could impact the safety of guests, passengers and personnel, equipment or the work environment.

The **identification** of a hazard provides an **opportunity to learn** how to prevent accidents and incidents it might cause.

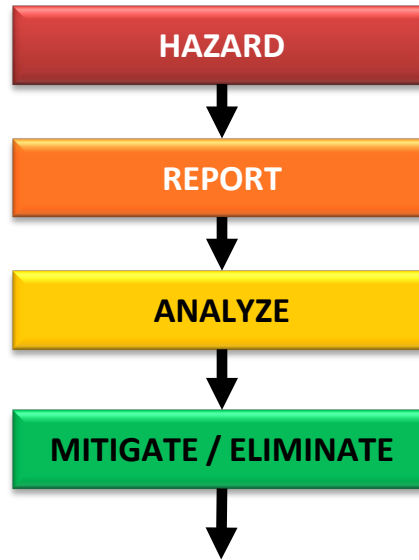
Procedures need to be in place for **internal reporting** of hazards. Timely collection of information allows the organization to react to the information.

A **hazard reporting form** should be **simple, convenient and available** to all employees.

Internal Hazard & Occurrence Reporting



Internal Hazard & Occurrence Reporting



Finally increase the level of safety! ✓

Risk Register

GM3 ORO.GEN.200(a)(3)

The **results of the assessment** of the potential adverse consequences or outcome of each hazard may be **recorded** by the operator **in a risk register**, an example of which is provided below.

Risk Register

Hazard		Incident Sequence Description	Existing Controls	Outcome (Pre-Mitigation)			Additional Mitigation required	Outcome (Post-Mitigation)			Actions and Owners	Monitoring and Review Requirements
No.	Description			Severity	Likelihood	Risk		Severity	Likelihood	Risk		

Occurrence Reporting to CAA

ORO.GEN.160 Occurrence reporting

(a) The operator shall **report to the competent authority**, and to any other organisation required by the State of the operator to be informed, **any accident, serious incident and occurrence** as defined in Reg. (EU) No 996/2010 of the European Parliament and of the Council and Directive 2003/42/EC.

NOTE: Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a **list classifying occurrences in civil aviation to be mandatorily reported**.

Occurrence Reporting to CAA

ORO.GEN.160 Occurrence reporting

(b) Without prejudice to point (a) the operator shall **report to the competent authority and to the organisation responsible for the design of the aircraft** any **incident, malfunction, technical defect, exceeding of technical limitations or occurrence** that would highlight inaccurate, incomplete or ambiguous information contained in the operational suitability data established in accordance with Regulation (EU) No 748/2012 or other irregular circumstance that has or **may have endangered the safe operation of the aircraft** and that has not resulted in an accident or serious incident.

Occurrence Reporting to CAA

ORO.GEN.160 Occurrence reporting

(c) Without prejudice to Reg. (EU) No 996/2010, Directive 2003/42/EC, Commission Reg. (EC) No 1321/20073 and Commission Reg. (EC) No 1330/20074, the **reports** referred in paragraphs (a) and (b) shall be **made in a form and manner established by the competent authority** and contain all pertinent information about the condition known to the operator.

Occurrence Reporting to CAA

ORO.GEN.160 Occurrence reporting

- (d) Reports shall be made as soon as practicable, but in any case **within 72 hours** of the operator identifying the condition to which the report relates, unless exceptional circumstances prevent this.
- (e) **Where relevant**, the operator shall **produce a follow-up report** to provide details of actions it intends to take to prevent similar occurrences in the future, as soon as these actions have been identified. This report shall be produced in a form and manner established by the competent authority.

Occurrence Reporting to CAA

AMC1 ORO.GEN.160 Occurrence reporting

- (a) The operator should **report all occurrences defined in AMC 20-8**, and as required by the applicable national rules implementing Directive 2003/42/EC5 on occurrence reporting in civil aviation.
- (b) In addition to the reports required by AMC 20-8 and Directive 2003/42/EC, the operator should **report volcanic ash clouds encountered during flight**.

Risk Based Oversight Group Activity

Group Exercise

Given:

Inspector receives an application from an air operator (ACMI) with a good score to enhance the operator specification from CAT I to Part SPA.LVO.100 CAT IIIa and LVTO 125m RVR. The reason for this application was the change of aircraft type from ATR 42 to EMB 190 aircraft type. The aircraft type E 190 was already implemented, and crew training was completed since almost one year. Therefore the operator operates four E 190 since one year under CAT I without any incidents and accidents. Based on experience during the last winter, the operator wants to start with CAT IIIa operation and LVTO 125 at least October 1st due to the new winter flight plan and due to standing request from new code share partners. We have June now! The application package contains all needful information, such as OM changes, Training syllabi, timelines etc.. The operator seeks for the approval getting started with training ASAP...

Group 1

You are the CAA Inspector / Inspectorate.

How you will tackle this application?

Can you agree on that the timeline 1st October for Ops Spec endorsement for Part SPA.LVO 100 is realistic?!

If no, please research for related arguments not to do as requested and set up new appropriate timelines ...

If yes, please state an appropriate timeline and approval scenario.....

Reference: Eu Reg. 965/2012 Part SPA.LVO.100

Group 2

You are the operator and must get the LVO Approval for CAT IIIa and LVTO until October 1st. As a matter of fact, if not – you will lose almost 90 % of your business as all code share partners want to continue only if the company can achieve this with given timelines. You operate the E 190 aircrafts without any problems. You have employed well trained TRI /TRE with experience on SPA.LVO operations from other operators. The aircrafts are all certified for Autoland. The simulators are booked for training. First training should start next week to meet the requirement from the aviation industry. You have set up all associated manual changes, training syllabi, technical changes are done on the airworthiness side. So you feel that you need a quick approval as you did everything on paper and on the technical side. You are convinced that you did also everything to meet legal requirements. Your problem is the remaining time frame...Convince the CAA during the discussion that they will approve your application in a timeline quick manner.

Reference: Eu Reg. 965/2012 Part SPA.LVO.100

Group exercise

Discuss and prepare with the group members 45 Minutes.

Come to a decision and prepare arguments for supporting purposes.

Attend as Group member the application meeting with the CAA.

Time 30 Minutes...

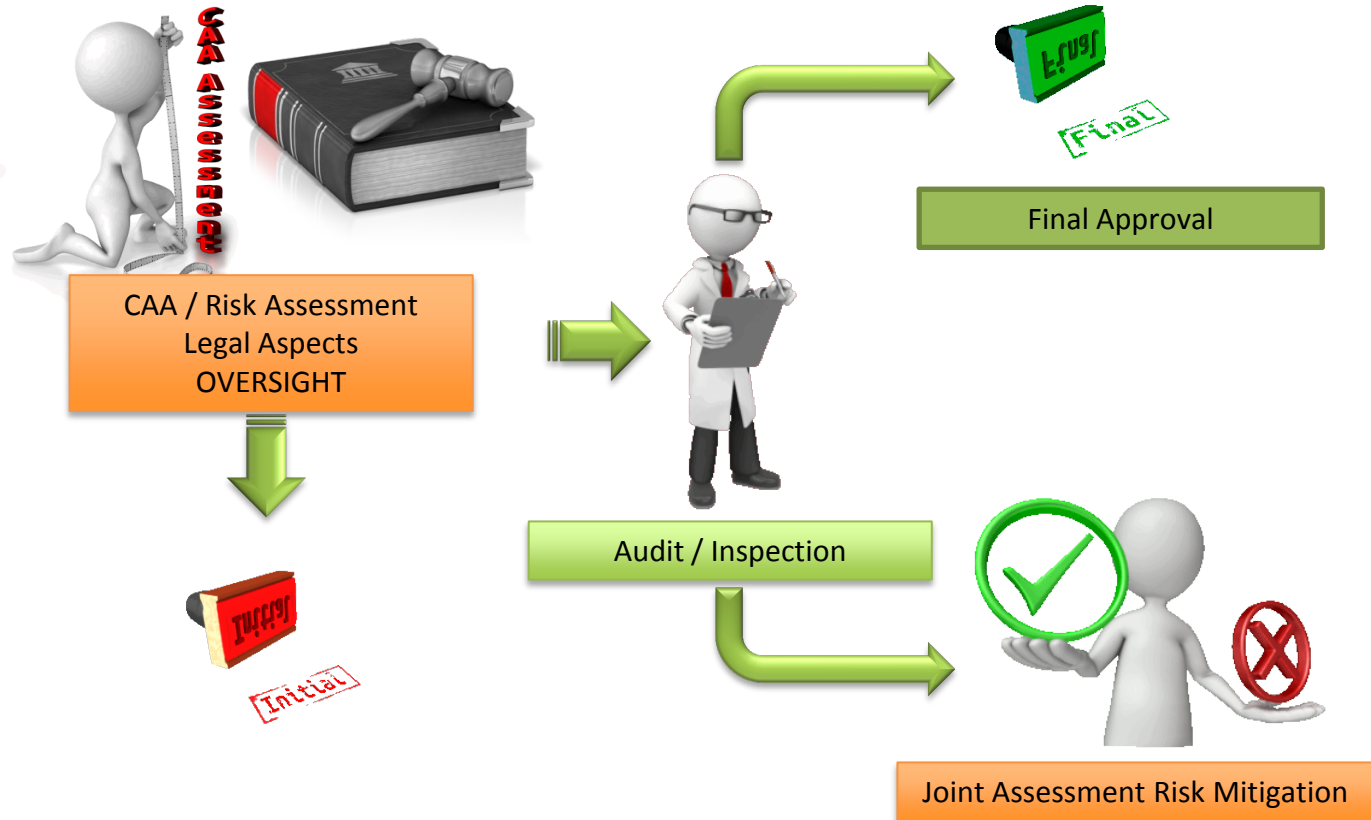
Group 1 → CAA section manger, Inspectors

Group 2 → Accountable Manager, Nominated Person Flight Operation, Nominated Person Crew Training, Nominated Person Maintenance, Nominated Person Ground Operation, Compliance Manger and Safety Manger

PROPOSED PERFORMANCE BASED CAA APPROVAL PROCESS BASED ON PRINCIPLES OF SMS/RM/RBO



PROPOSED PERFORMANCE BASED CAA APPROVAL PROCESS BASED ON PRINCIPLES OF SMS/RM/RBO



RBO Benefits – A Regulators View

Safety management

risk management capabilities in a flexible framework

better allocation of resources to address the risks identified

Resilience

regulatory framework capable of anticipating and self-adapting to change

response to increased complexity, new business models and technological development

Flexibility

focus on safety outcomes encouraging innovation

means to control specific risks not restricted in priority

“Without pioneers, the world will turn but never move forward”



END OF COURSE

Thank you 😊



Any question?

www.eu-sea-app.org
easa.europa.eu/connect



Your safety is our mission.

An Agency of the European Union 