



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

# Design Organisation Approval (Part 21 DOA) Implementation workshop with industry

29-30 November 2011  
RHEIN/RUHR/ERFT Conference Rooms,  
Hermann Pünder Straße 1  
Köln – Germany

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# Independent System Monitoring

The “Process” approach

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# Summary

1. Regulatory basis
2. ISO 9000 – The process approach
3. Process monitoring
4. Collection of data
5. Analysis – Corrective actions
6. Feed back system
7. Quality assurance System
8. Mixed solution



# Regulatory basis

The Independent System Monitoring requirements are documented in Part 21A.239 (a) 3 and related GM:

## **21A.239 Design assurance system**

(a) The design organisation shall demonstrate that it has established and is able to maintain a design assurance system for the control and supervision of the design, and of design changes, of products, parts and appliances covered by the application. This design assurance system shall be such as to enable the organisation:

1. ...

...

3. To independently monitor the compliance with, and adequacy of, the documented procedures of the system. This monitoring shall include a feed-back system to a person or a group of persons having the responsibility to ensure corrective actions



## **GM No. 1 to 21A.239(a) Design assurance system**

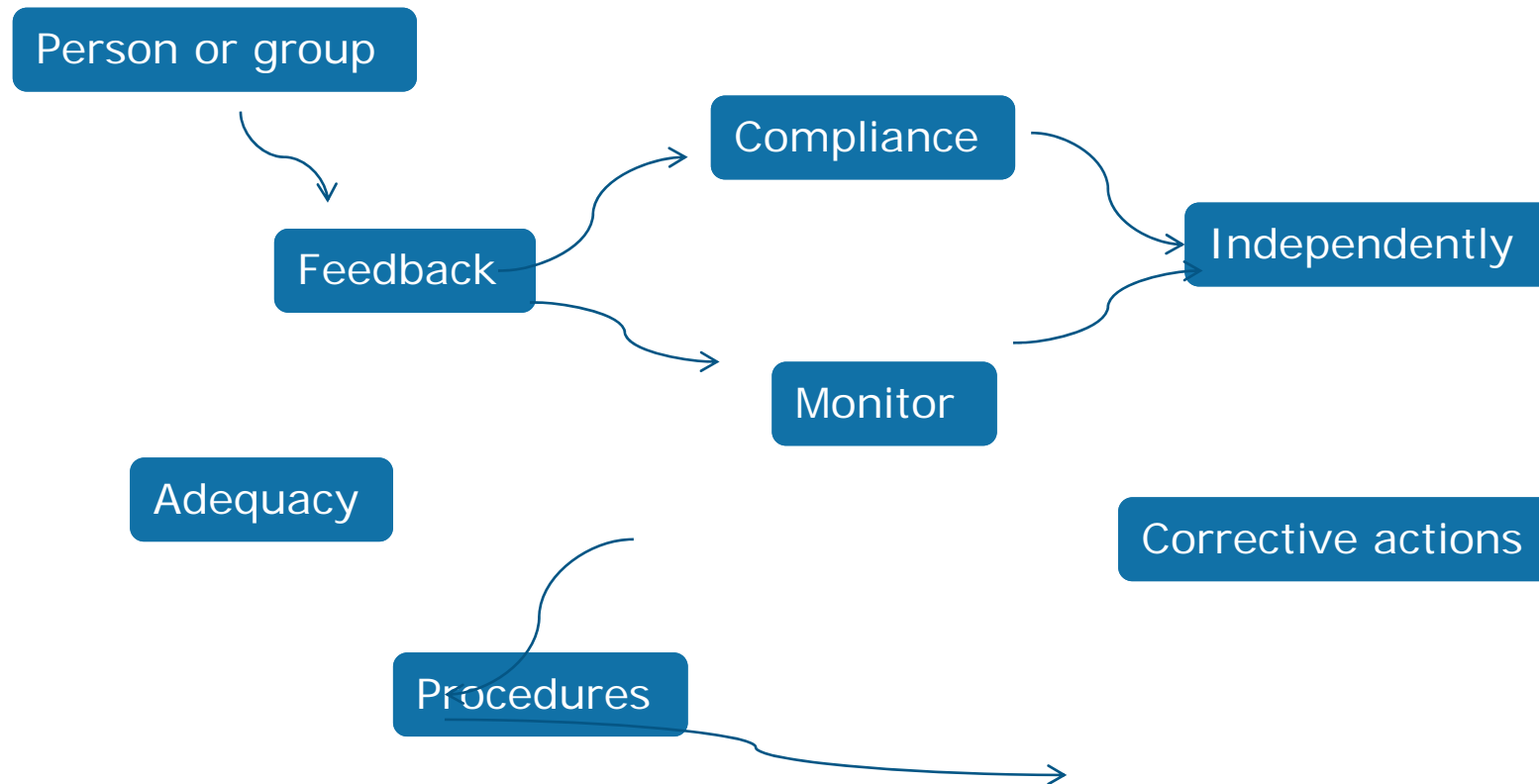
3.2 Continued Effectiveness of the design assurance system. The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

## **AMC 21A.239(a)(3) Design assurance system - Independent system monitoring**

The system monitoring function required by 21A.239(a)(3) may be undertaken by the existing quality assurance organisation when the design organisation is part of a larger organisation.



## KEYWORDS





# ISO 9000 – The process approach

## SYSTEM AND PROCESSES

- ❖ All systems (including the design assurance system) are made of processes.
- ❖ Processes have input and outputs.
- ❖ Outputs are called “deliverables”.
- ❖ Processes may interact.
- ❖ Processes have process owners.
- ❖ Processes have process operators playing “roles”.
- ❖ Processes are made of tasks allocated to roles.
- ❖ Processes may need tools (Databases, Forms...).
- ❖ Good health of the system must be evaluated via process monitoring.



# ISO 9000 – The process approach

## SYSTEM AND PROCESSES

System as a set of processes interacting together.







# ISO 9000 – The process approach

## Example of DOA processes

- ❖ Type Certification
- ❖ Major Changes
- ❖ STC
- ❖ Major Repair
- ❖ Minor Change
- ❖ Minor Repairs
- ❖ Occurrence reporting
- ❖ Independent System Monitoring
- ❖ Management of DOA
- ❖ Competences
- ❖ Supplier control
- ❖ ...



# ISO 9000 – The process approach

## Example of DOA Deliverables

- ❖ Drawings
- ❖ Digital mock-up
- ❖ Certification basis
- ❖ Certification programme(s)
- ❖ Specifications
- ❖ Compliance documents
  - ❖ Analysis
  - ❖ Test reports
  - ❖ Qualification
- ❖ Certification summary
- ❖ Master Data List
- ❖ Flight Conditions
- ❖ Permit to fly
- ❖ ...



# Process monitoring

## Effective monitoring

- ❖ Technical content of the deliverables.
- ❖ Process adherence (compliance with procedures).
- ❖ Monitoring and analysis at process level performed by competent staff (“métier”).
- ❖ Systematic collection of issues arising during a given process (e.g. difficulties or good performances during change or STC process).
- ❖ Systematic and complete reporting about health of the process (performance and not only non conformities).

## Process owners

- ❖ They may participate themselves or by delegation in the design of the process and demonstrate compliance with the requirements.
- ❖ They may participate themselves or by delegation to the monitoring and assess the performance of the process operators.
- ❖ They have the knowledge to analyse the performance of their process.
- ❖ They should report to the upper monitoring level.

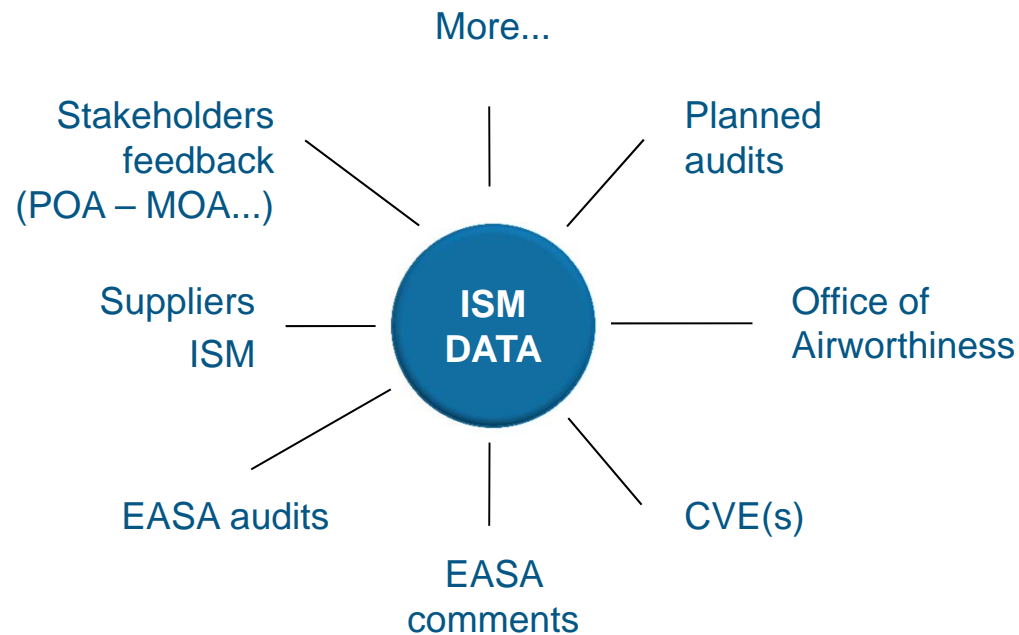


Example of process monitoring at process level

VIDEO REMOVED IN THIS VERSION (LIGHT WEIGHT)



# Collection of data



**Data to be collected, like performance indicators, need to be clearly identified and instructions given to all actors.**



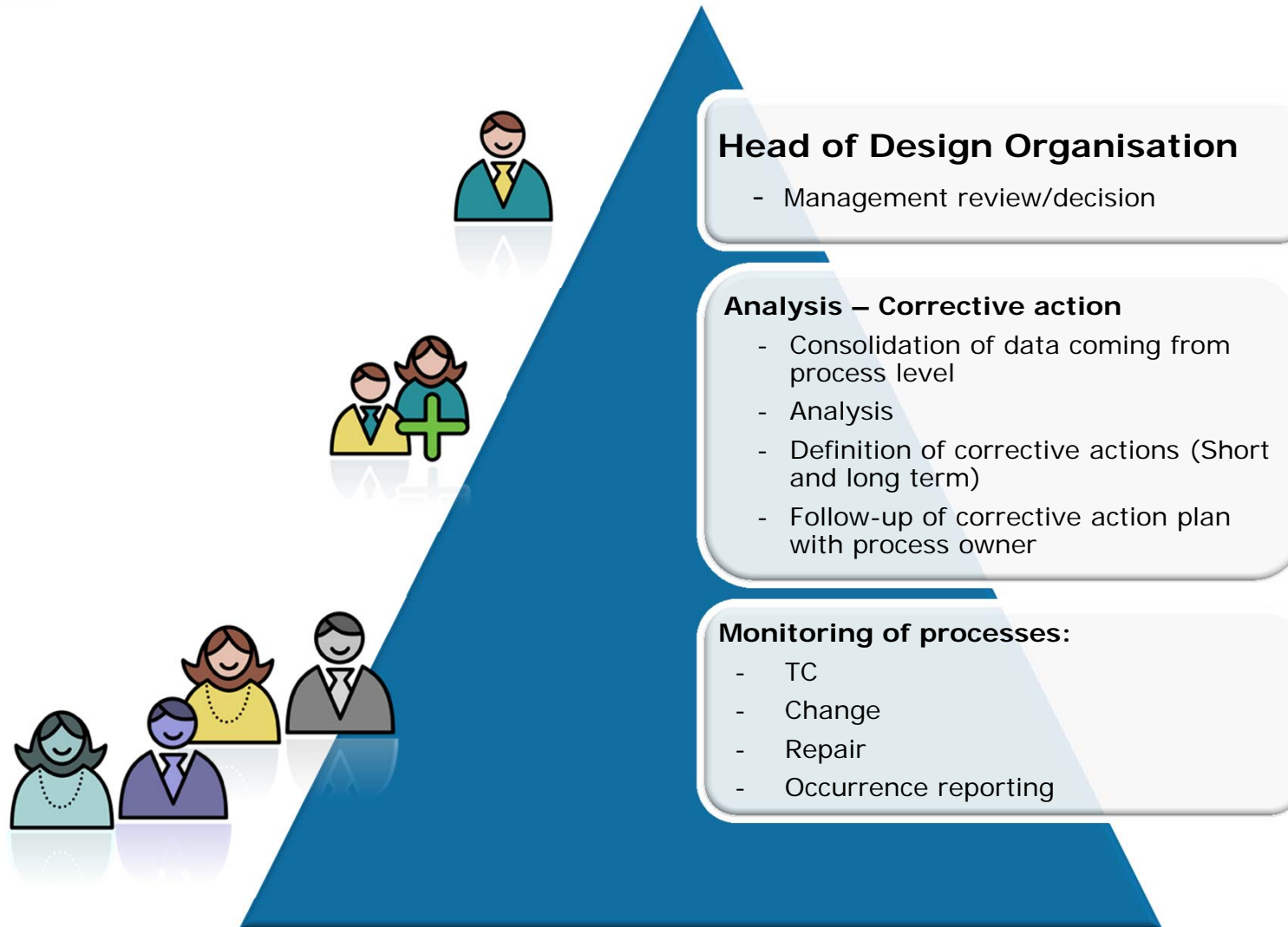
# Analysis – Corrective actions

**A person or a group of persons having the responsibility to ensure corrective actions...**

- ❖ Above process owner level and below the Head of Design organisation position (or by Head of Design Organisation her/himself).
- ❖ Part 21 experts. Part 21 is an airworthiness referential. EN9100, for example, is a quality referential.
- ❖ Supporting process owners in defining processes compliant with Part 21.
- ❖ Supporting process owners in the analysis of the root cause of the issues collected during process monitoring.
- ❖ Supporting process owners in defining corrective actions.
- ❖ Supporting process owners in verifying the effectiveness of the corrective actions.
- ❖ Liaising with the EASA DOATL.
- ❖ Reporting summarised information related to Design Assurance System performance / health to the Head of Design Organisation.



# Feedback system





# Quality Assurance Organisation

## And the Quality?

The system monitoring function required by 21A.239(a)(3) may be undertaken by the existing quality assurance organisation...

Under the condition that:

- ❖ The Quality Organisation has demonstrated the competences required to perform the process monitoring (see slide 11).
- ❖ The Quality Organisation has demonstrated a proper level of expertise of the Part 21.
- ❖ The Quality Organisation has demonstrated the competences required to perform the analysis and to define the corrective actions (see slide 13).





# Mixed solution

## Person or group of persons

Process  
owner



Quality



DOA  
management



Together contributing to the monitoring of a  
process:





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**END**

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