



**EASA**  
European Aviation Safety Agency

# **Product Certification and Design Organisation Approval Workshop**

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**Your safety is our mission.**

An agency of the European Union 

TE.GEN.00409-001



**EASA**  
European Aviation Safety Agency

# Independent System Monitoring

## The “Process” approach

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**23rd November 2016**

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# Summary

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2. ISO 9000 – The process approach
3. ISM keywords
4. System Monitoring → Process monitoring
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# 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. ...
    2. ...
  - 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



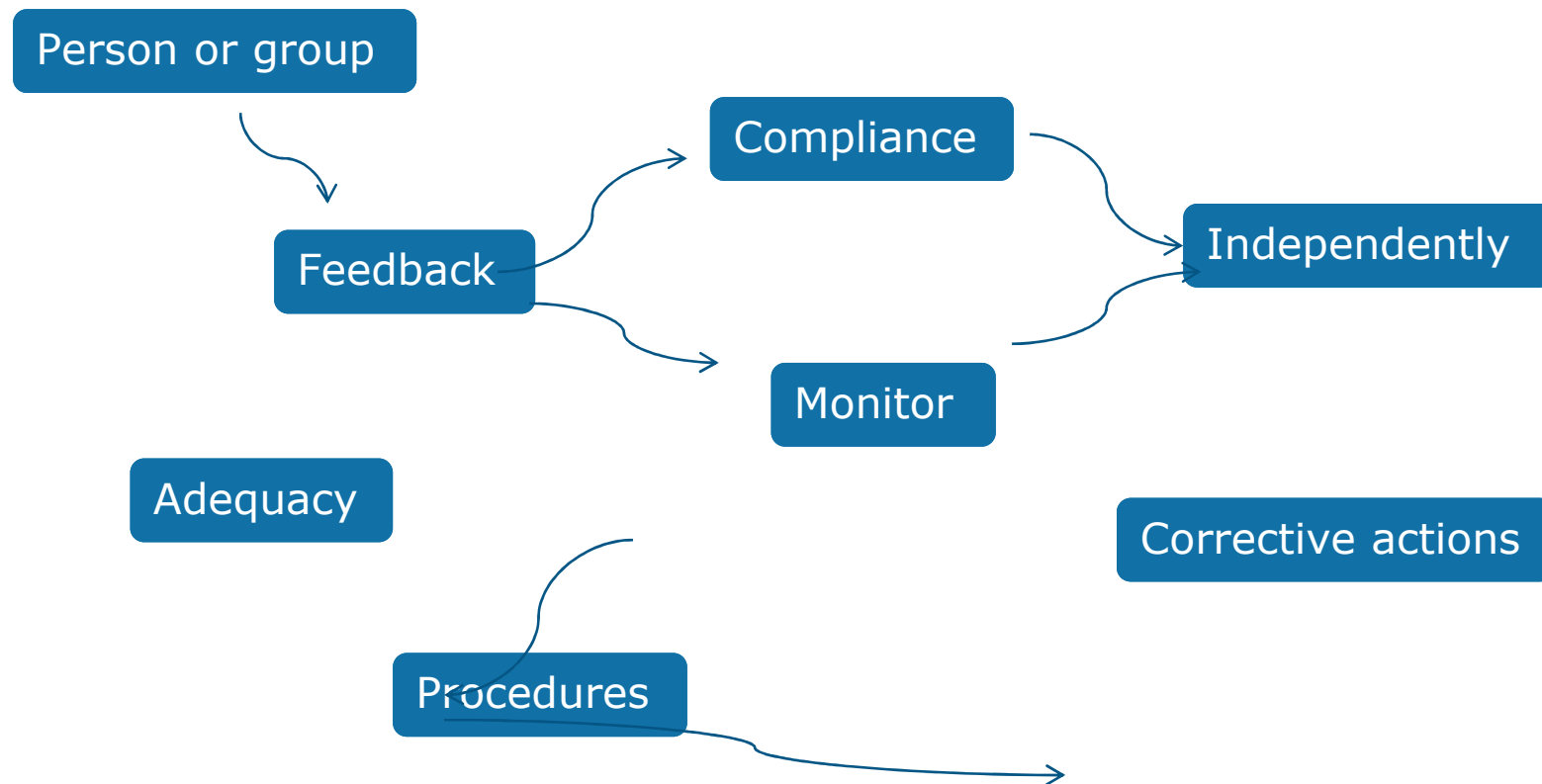
# Regulatory basis

- **GM No. 1 to 21A.239(a) Design assurance system**
- 2 Definitions. The design assurance system is the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation
- 2. Definitions. The design assurance means all those planned and systematic actions necessary to provide confidence that the organisation has the capacity to..
- 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.



# ISM Keywords

## ► KEYWORDS





# What does the ISM do?

- ISM function independently monitor the compliance with, and adequacy of, the procedures of the design assurance system
- The procedures contain planned and systematic actions to enable the organisation to perform its “design activities” (wider sense)
- To perform design activities in an effective manner and in compliance with procedures, an organisation needs a structure, assigned responsibilities, and resources
- Ultimately, the ISM function audits the organisation to ensure activities are performed in accordance with procedures, and where necessary, a person or a group of persons improves the activities and the procedures



# 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 resources/tools (Databases, Forms...).
- ❖ Performance of the system must be evaluated via process monitoring.





# 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
- ❖ ...



# System monitoring → Process monitoring

## ➤ **Effective process monitoring:**

- ❖ Process adherence (compliance with the procedures of the process)
- ❖ Technical content of the deliverable to meet its purpose/objective
- ❖ Competences of the process owners/operators with respect to assigned responsibilities and tasks
- ❖ Adequacy of resources/tools to perform tasks of the process
- ❖ Sufficiency of the inputs to be elaborated by the personnel
- ❖ Adequacy of procedures to the scope of work activities and for demonstrating compliance with Part 21 requirements



# System monitoring → Process monitoring

## ➤ Adequacy of procedures:

- ❖ Available: documented, controlled and accessible to process operators / personnel
- ❖ Workable: they contain sequence of steps (who, what, when, where, how) and **not only** policy statement (why);
- ❖ Intelligible: simple language and simple structure; consistent; no unnecessary fragmentation
- ❖ Compliant and complete: compliant with Part 21; covering all process; containing proper cross-references;
- ❖ Known: personnel is trained before being assigned a responsibility/task within a process



# System monitoring → Process monitoring

## ➤ Process Owners

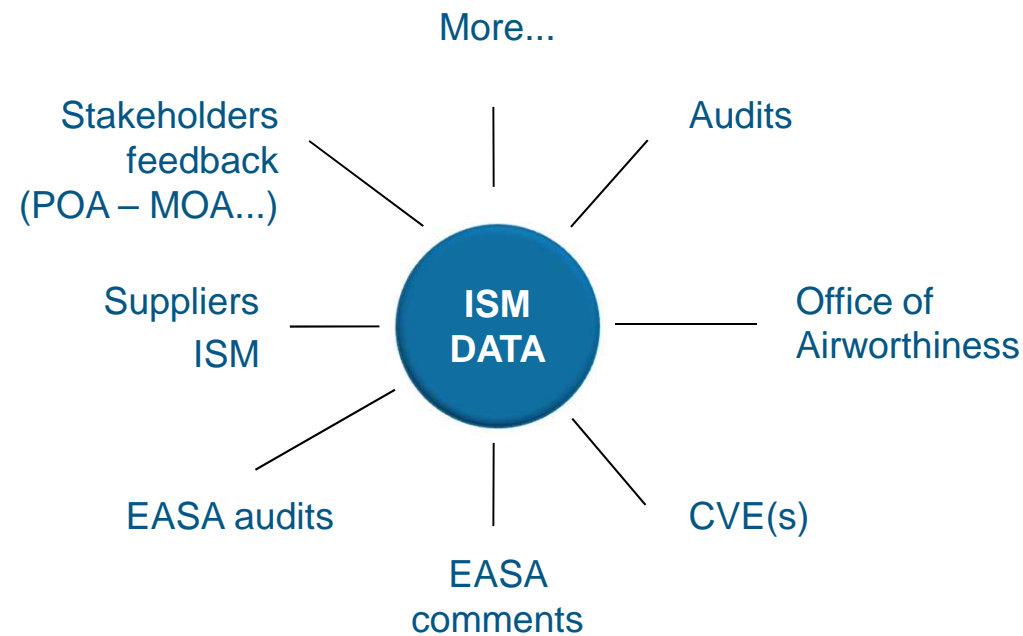
- ❖ They are responsible for the proper functioning of the process, and therefore should oversee all the elements of a process: procedures, resources, inputs, outputs, personnel
- ❖ They shall have the knowledge to analyse the performance of their process.
- ❖ They should report to the independent monitoring function the performance of the process and actively contribute to the introduction of corrective actions of identified non-compliance and issues.

## ➤ Process Operators

- ❖ They are performing the steps (task) of the process and might be responsible for sub-process (sub-sequence of the steps of a process)
- ❖ They should actively contribute to the drafting and update of procedures
- ❖ They should report to the process owners eventual issues encountered in the performance of assigned tasks.



# ISM relevant Information





# Analysis of ISM info – Corrective actions

- **A person or a group of persons having the responsibility to ensure corrective actions...**
- ❖ Together with process owners, they analyse ISM info to determine the root causes of the issues identified during process monitoring.
- ❖ This requires a big picture approach and they should be above process owner level and below the Head of Design organisation position (or by Head of Design Organisation her/himself).
- ❖ They should be Part 21 experts. Part 21 is an airworthiness referential. EN9100, for example, is a quality referential.
- ❖ They support process owners in defining processes compliant with Part 21 and corrective actions when deficiencies are identified.
- ❖ They also support process owners in verifying the effectiveness of the corrective actions.
- ❖ They liaise with the EASA DOATL.
- ❖ They report summarised information related to Design Assurance System performance / compliance to the Head of Design Organisation.



# “Human factor” Survey by Human Reliability Associates Ltd

- Procedures are not used because (percentage agreeing):
  - Accuracy
    - They are inaccurate 21%
    - They are out-of-date 45%
  - Practicality
    - They are unworkable in practice 40%
    - They make it more difficult to do the work 42%
    - They are too restrictive 48%
    - Too time consuming 44%
    - If they are followed to the letter the job could not get done on time 62%
  - Optimisation
    - People usually find better way of doing the job 42%
    - They do not describe the best way to carry out the work 48%



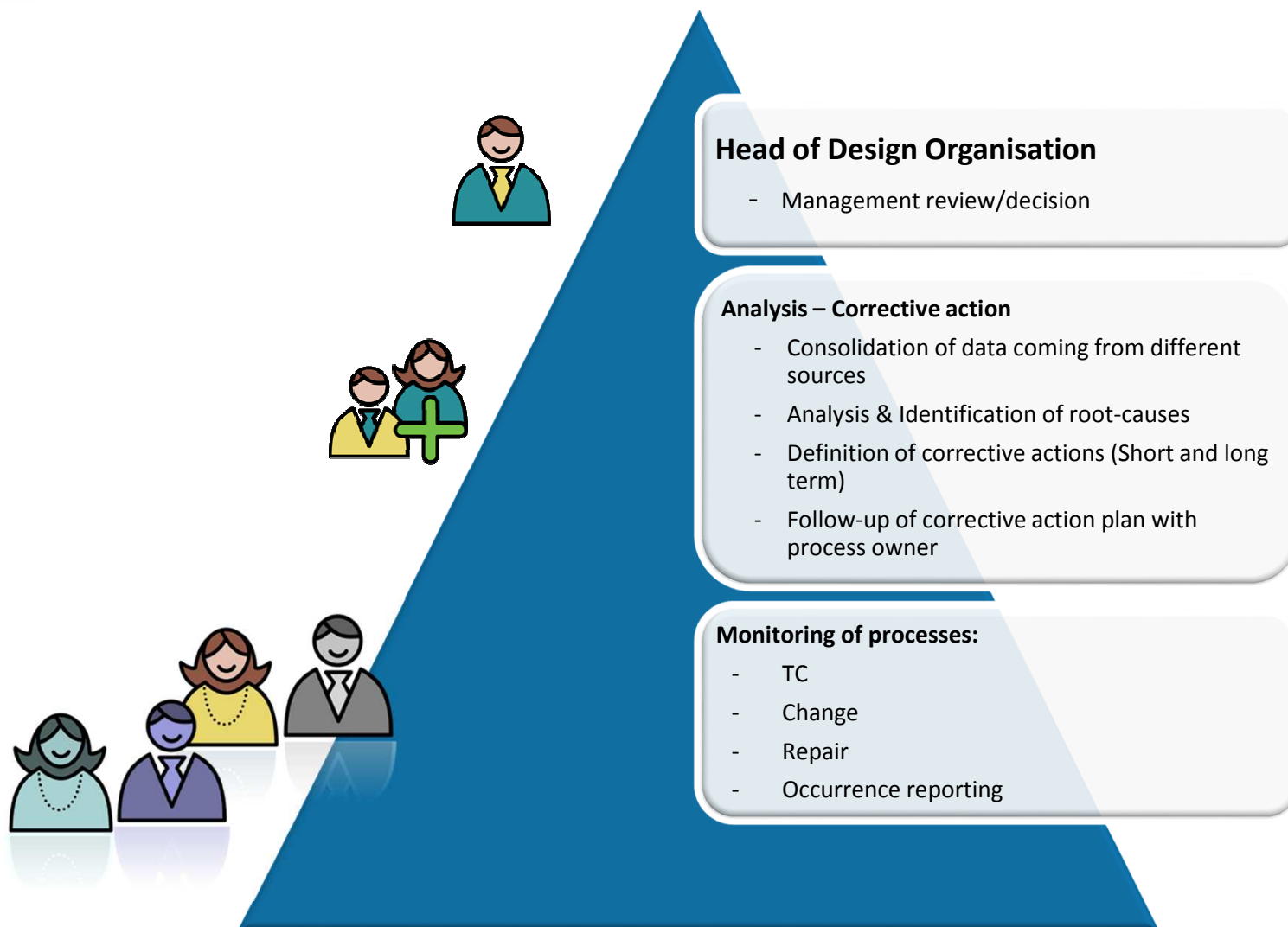


# “Human factor”

- Procedures are not used because (percentage agreeing):
  - Presentation
    - It is difficult to know which is the right procedure 32%
    - They are too complex and difficult to use 42%
    - It is difficult to find the information you need within the procedure 48%
  - Accessibility
    - It is difficult to locate the right procedure 50%
    - People are not aware a procedure exists for the job they are doing 57%
  - Policy
    - People do not understand why they are necessary 40%
    - No clear policy on when they should be used 37%
  - Usage
    - Experienced people do not need them 19%
    - People resent being told how to do their job 34%
    - People prefer to rely on their own skills and experience 72%
    - People assume they know what is in the procedure 70%



# 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:

