



EASA
European Aviation Safety Agency

Standardising Multiple National Systems in Aviation and Medicine

—

Challenges and Limitations

Your safety is our mission.

An agency of the European Union 



Standardisation events



today known as



The International Organization for Standardization

- ISO is derived from the Greek *isos* - equal



Disclosure

- We have no actual or potential conflict of interest in relation to this program/presentation.



Why?

Basic principle

Overall objective: to establish and maintain a high uniform level of civil aviation safety in Europe



REGULATION (EU) No 2018/1139

(1)

A high and uniform level of civil aviation safety should be ensured at all times by the adoption of common safety rules and by measures ensuring that any goods, persons and organisations involved in civil aviation activity in the Union comply with such rules.

(57)

With a view to contributing to the uniform application of this Regulation, **the Agency should be empowered to monitor such application by Member States, including by conducting inspections.**

Article 75

Establishment and functions of the Agency

the Agency shall (e) **conduct inspections, other monitoring activities and investigations** as necessary to fulfil its tasks under this Regulation, or as requested by the Commission;



Why?

Basic principle

Overall objective: to establish and maintain a high uniform level of civil aviation safety in Europe

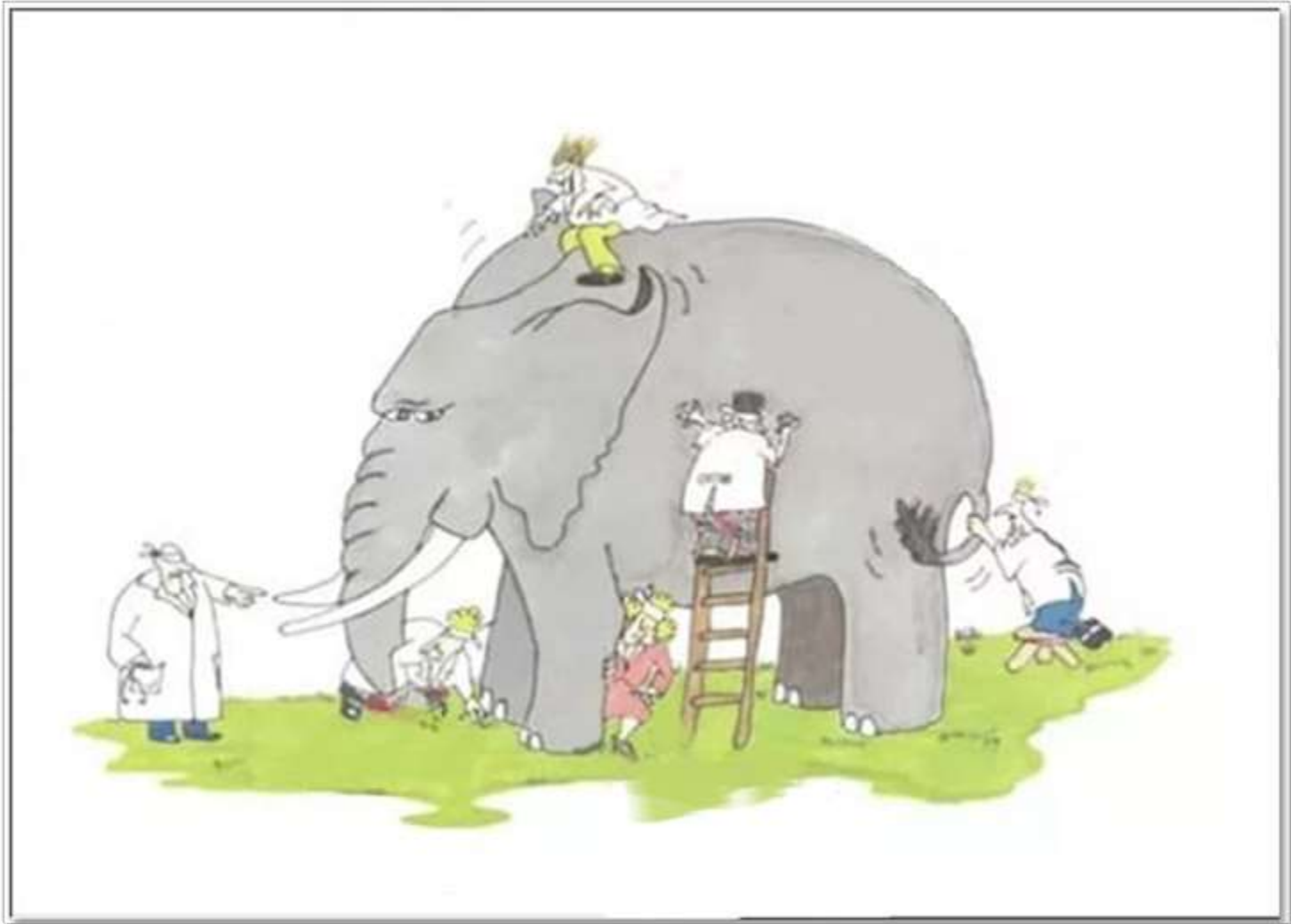
Standardisation inspection's objective:

Monitoring NAA - how they are implementing EU rules:

- Not less than required → to protect EU citizens
- Not more than required → to ensure a level playing field

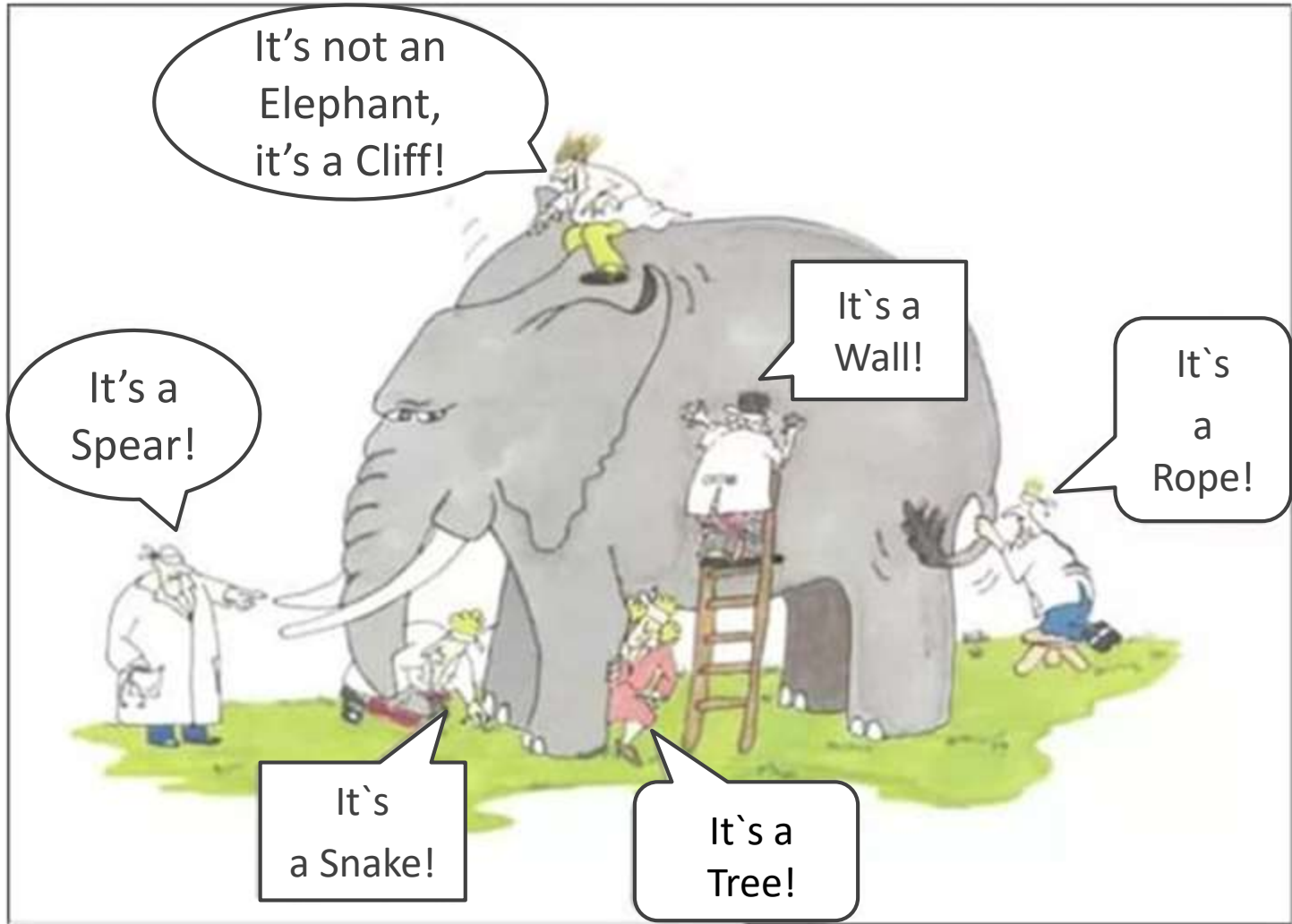


What?





What?





Standardisation

What:

- The activity and performance of Member States (MS) are tracked and used to target inspections of MS' Competent Authorities
 - These inspections may include visits to undertakings or associations of undertakings under the oversight of the Competent Authority inspected
- Findings are progressed with States and in critical cases EASA works with the Commission to enforce action.

Where:



EU	28 +
EFTA	4 +
WA	14 =
Total	46 countries
(SAFA 44)	

How:

- 100+ inspections/year
- 800+ findings raised/year

In addition:

- Involvement of MS' inspectors
- Standardisation Meetings with MS'
- Inspectors' training
- Targeted support to Authorities
- Regulatory feedback



What?



Monitor the application by the CA of Basic Regulation and its Implementing Rules in **Aircrew MED** and **ATCO MED** domain and assess their uniform implementation

Assess the CA's ability to discharge its safety oversight responsibilities

Gather information in the context of the Continuous Monitoring Approach

Collect information regarding the impact of implementation of BR and its IR

Follow-up findings raised in previous inspections

Report the above to the Commission



What?

The final report of the standardisation inspection
shall be
addressed to **the competent authority inspected
and to the Commission;**



Who?

Team composition – Reg. 628/2013



Article 11

Training, qualification and authorisation criteria for inspection teams

Team leaders shall be personnel employed by the Agency.

Team members shall be personnel employed by the Agency or seconded personnel.

Article 12

Setting up teams for inspections

Each team shall have a team leader and one team member as a minimum.

In all cases, the Agency shall ensure the size of the teams remains commensurate to the scope.



Who? Team Members

REGULATION (EU) No 2018/1139

The Agency shall ensure that the members of its staff and, where relevant, any other expert participating in the inspection or the other monitoring activity are

sufficiently qualified and adequately instructed.

In the case of inspections, those persons shall exercise their powers upon production of a written authorisation.



Who? Team Members

Regulation (EU) No 628/2013

Article 4

Principles applicable to inspections and findings

4. Inspections shall be carried out by a team composed of personnel authorised by the Agency, which shall **be qualified and trained in their respective domain(s)**.

Authorised personnel shall apply the principles of independence, integrity, ethical conduct, due diligence, fair presentation and **confidentiality**.

Article 11

Training, qualification and authorisation criteria for inspection teams

1. The Agency shall establish qualification criteria for the personnel who participate in inspection teams.

2. The qualification criteria shall include:

(a) knowledge of the institutional and regulatory framework, in particular of this Regulation as well as on the relevant international agreements;

(b) knowledge and experience of auditing techniques;

(c) technical competence and practical experience in the relevant domain(s)



Who?

Aircrew and Medical Section



**Dr. Janis
Vegers**



**Dr. Virgilijus
Valentukevicius**



**Dr. Cristian
Panait**



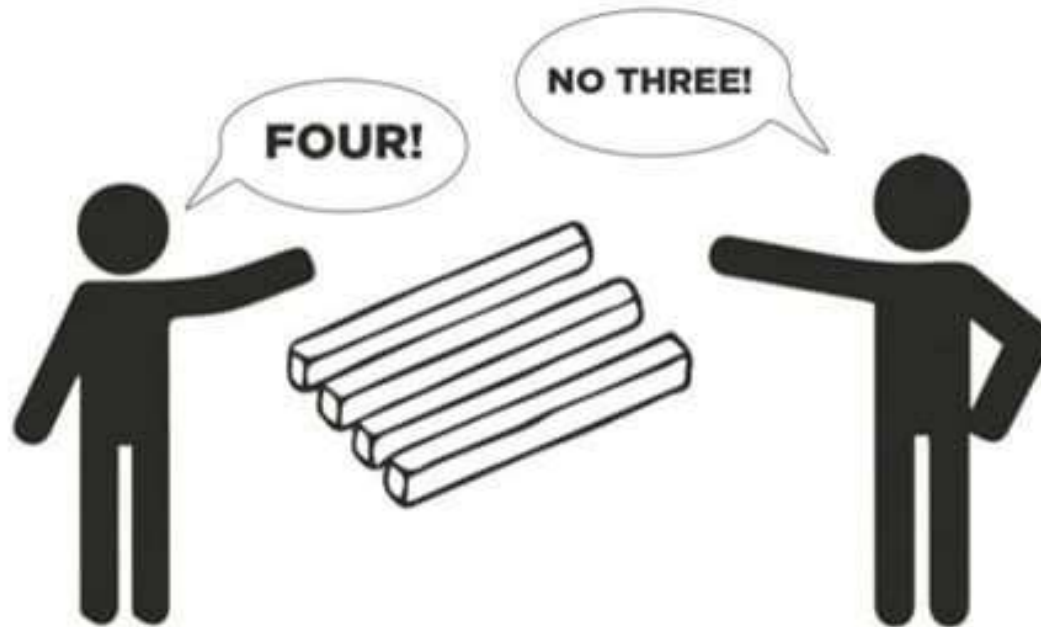
Who? Team Members

- 9 qualified Team Members + 1 EASA;
- 1 TM on training

- 12 - 14 medical standardisation inspections per year



Standardisation





How?

REGULATION (EU) No 2018/1139

Article 75

Establishment and functions of the Agency

the Agency shall :

(e) **conduct inspections, other monitoring activities and investigations** as necessary to fulfil its tasks under this Regulation, or as requested by the Commission;



How?

Regulation (EU) No 628/2013

Article 13

Conduct of inspections

1. Inspections referred to in Article 10(1)(a) and (b) shall include the following phases:

(a) **a preparatory phase,**

lasting a minimum of 10 weeks prior to the inspection;

(b) **an on-site phase;**

(c) **a reporting phase,**

lasting a maximum of 10 weeks following the end of the on-site phase.



How?

Types of inspections

Comprehensive Inspection

- To inspect one or more domains at intervals determined by the outcome of continuous monitoring

Focused Inspection

To inspect specific areas within one or more domains and/or to assess the implementation of corrections and corrective actions

Ad Hoc Inspection

- To investigate specific concerns arising from continuous monitoring or upon request from the Commission

Off-site Finding



- When the Agency has sufficient evidence to substantiate a finding without performing an inspection on-site



How?

- Standard auditing techniques
 - **Interviews;**
 - **Review of documents and records;**
 - **Sampling of processes**
- The team is empowered to examine and take copies of documents and records.



REGULATION (EU) No 2018/1139

Article 85

Monitoring of Member States

2. the Agency shall be empowered to:

- (a) **require** any national competent authority and any natural and legal person subject to this Regulation **to provide the Agency with all necessary information**;
- (b) **require** those authorities and persons **to provide oral explanations on any fact, document, object, procedure** or other subject matter relevant for determining whether a Member State complies with this Regulation and with the delegated and implementing acts adopted on the basis thereof;
- (c) **enter relevant premises, land** and means of transport of those authorities and persons;
- (d) **examine, copy or make extracts from any relevant document, record or data** held by or accessible to those authorities and persons, irrespective of the medium on which the information in question is stored.



How?

- Standard auditing techniques
 - **Interviews;**
 - **Review of documents and records;**
 - **Sampling of processes**
- The team is empowered to examine and take copies of documents and records.
- Regular progress meetings with the NAA (NSC/SFP):
 - Progress of inspection;
 - Transfer of information;
 - Validation of (potential) findings



How?

Plan of the visits

January	February	March	April Croatia C ATCO ACW Germany C ACW
May Norway C ACW Cyprus F ACW	June Romania C ATCO ACW Spain C ATCO F ACW	July United Kingdom C ATCO ACW	August
September Germany C ATCO Switzerland C ATCO ACW	October Italy C ATCO Greece C ATCO	November Finland C ATCO ACW Denmark F ACW	December Netherlands C ACW

ACW - Aircrew

COMMISSION REGULATION (EU) No 1178/2011 of 3 November 2011, all Parts and Annexes, as applicable.

ATCO

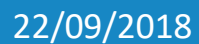
COMMISSION REGULATION (EU) No 340/2015 of 20 February 2015, all Parts and Annexes, as applicable.



How? Inspecting Phase 2 - On-site

AeMCs and AME`s are visited as samples to evaluate the oversight of the CA.

- ✓ **Good or Bad;**
- ✓ **Previously not visited;**
- ✓ **Or previously - UNC;**
- ✓ **Not close to CA;**
- ✓ **«whistleblowers».**





Common Findings

- ✓ Medical confidentiality is not respected at all times;
- ✓ Practical training for AME applicants extending their privileges to the revalidation and renewal of Class 1 medical certificates;
- ✓ Medical examination/ tests;
- ✓ Responsible person(s) for aeromedical tasks.



EASA
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Thank you

Questions?

Your safety is our mission.

An agency of the European Union

