EASA
European Aviation Safety Agency

ATCO Medical requirements: Standardisation Inspection Procedures

Cologne

9 July 2015

Your safety is our mission.

An agency of the European Union

IC.PRES.003-003

Legal basis

The Standardisation Inspection Process:

Article 2(1) of the BR defines its main objective as follows:

Article 2

Objectives

"The principal objective of this Regulation is to establish and maintain a high uniform level of civil aviation safety in Europe."

Legal basis

- COMMISSION IMPLEMENTING REGULATION (EU) No 628/2013 of 28 June 2013

on working methods of the European Aviation Safety Agency for conducting standardisation inspections and for monitoring the application of the rules of Regulation (EC) No 216/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 736/2006

Standardisation goals

Standardisation aims to ensure a **high** and **uniform** level of safety by monitoring how CAs apply EU Regulations in accordance with the "no more, no less" principle:

- **Not less** than required ⇨ to ensure a **high** level of **safety**
- **Not more** than required ⇨ to ensure a **uniform level** ("**even playing field**")

Standardisation goals

- Monitor the application by the Competent Authority of Basic Regulation and its Implementing Rules and assess their uniform implementation
- Assess ability of the Competent Authority 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 European Commission

Annual programme (SIAP)

- The SIAP is communicated to the Commission and to all the members of the Management Board of the Agency, as part of the Agency's annual work programme; thus, each Member State is informed about the timeframe in which a regular inspection is planned.

- However, the above does not apply to focused inspections, which can be organised by the Agency to assess the satisfactory completion of corrective actions from previous inspections, nor to the ad-hoc inspections, which can be requested from the Commission whenever deemed necessary for safety reasons.

Types of Standardisation Inspections

- Comprehensive inspections, for the purpose of inspecting one or more domains; these inspections shall be performed at intervals determined based on the results of the continuous monitoring
- Focused inspections, for the purpose of inspecting specific areas within one or more domains, and/or for the purpose of assessing the implementation status of agreed corrections and corrective actions
- Ad hoc inspections, for the purpose of investigating specific concerns arising from the Agency's continuous monitoring or upon request from the Commission
- Off-site findings

Conduct of Standardisation Inspections

Comprehensive Inspection phases:

- Preparatory phase, lasting a minimum of 10 weeks prior to the inspection
- On-site phase
- Reporting phase, lasting a maximum of 10 weeks following the end of the on-site phase

Preparatory phase

The Agency shall:

- give notice of the inspection to the competent authority at least 10 weeks before the on-site phase, including the intended type, domain(s) and areas for inspection
- collect the necessary information for the preparation of the inspection, taking duly into account the information available from continuous monitoring
- define the scope, the extent and the programme of the inspection, including the inspection of undertakings or association of undertakings, taking into account the information from continuous monitoring
- determine the size and the composition of the inspection team

On-site phase

The Agency shall:

- organise an opening meeting with the national standardisation coordinator and the competent authority inspected
- follow up findings of non-conformity identified in previous inspections and that remain open, and review the corresponding corrections and corrective actions
- notify the competent authority of any immediate safety concern, where such concern is identified during the inspection
- at a closing session, present to the competent authority inspected a list of preliminary findings of non-conformity identified or followed up in the course of the inspection

Reporting phase

The Agency shall:

- within 6 weeks after the closing session of the on-site phase, review the preliminary findings, classify them and establish on this basis a draft report addressed to the competent authority inspected
- prepare a draft report of the inspection
- within 10 weeks after the closing session, issue a final report on the basis of the draft report
- establish and maintain a continuous monitoring status for each Member State

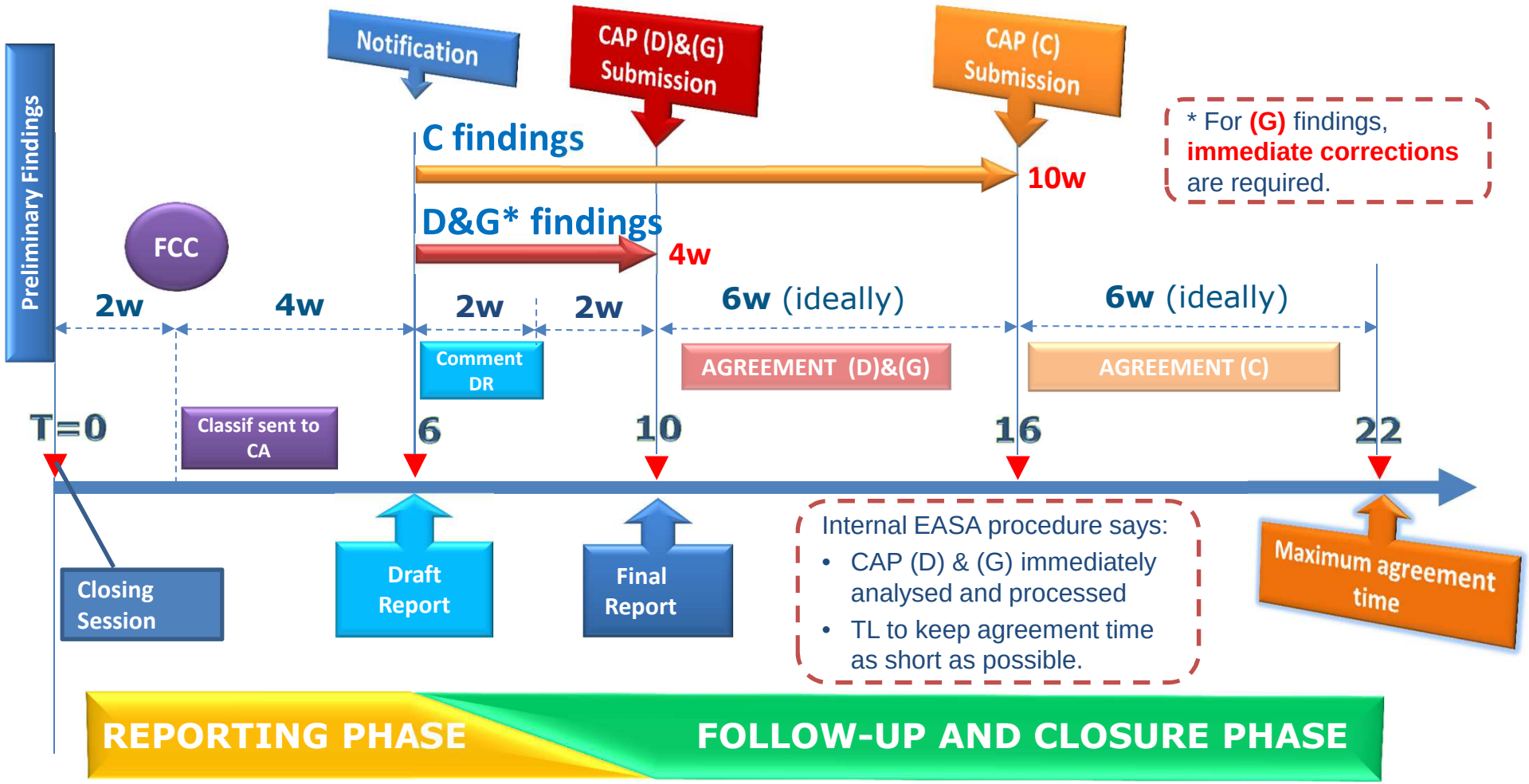
Classification of findings

All findings of non-conformity identified by the Agency in the framework of the inspections shall be classified as follows:

- Class C: non-conformity with the applicable requirements, raising mainly standardisation concerns
- Class D: non-conformity with the applicable requirements, raising standardisation concerns and safety concerns if not timely corrected
- Class G: immediate safety concern

Findings follow-up and closure

Findings managed and closed at individual level

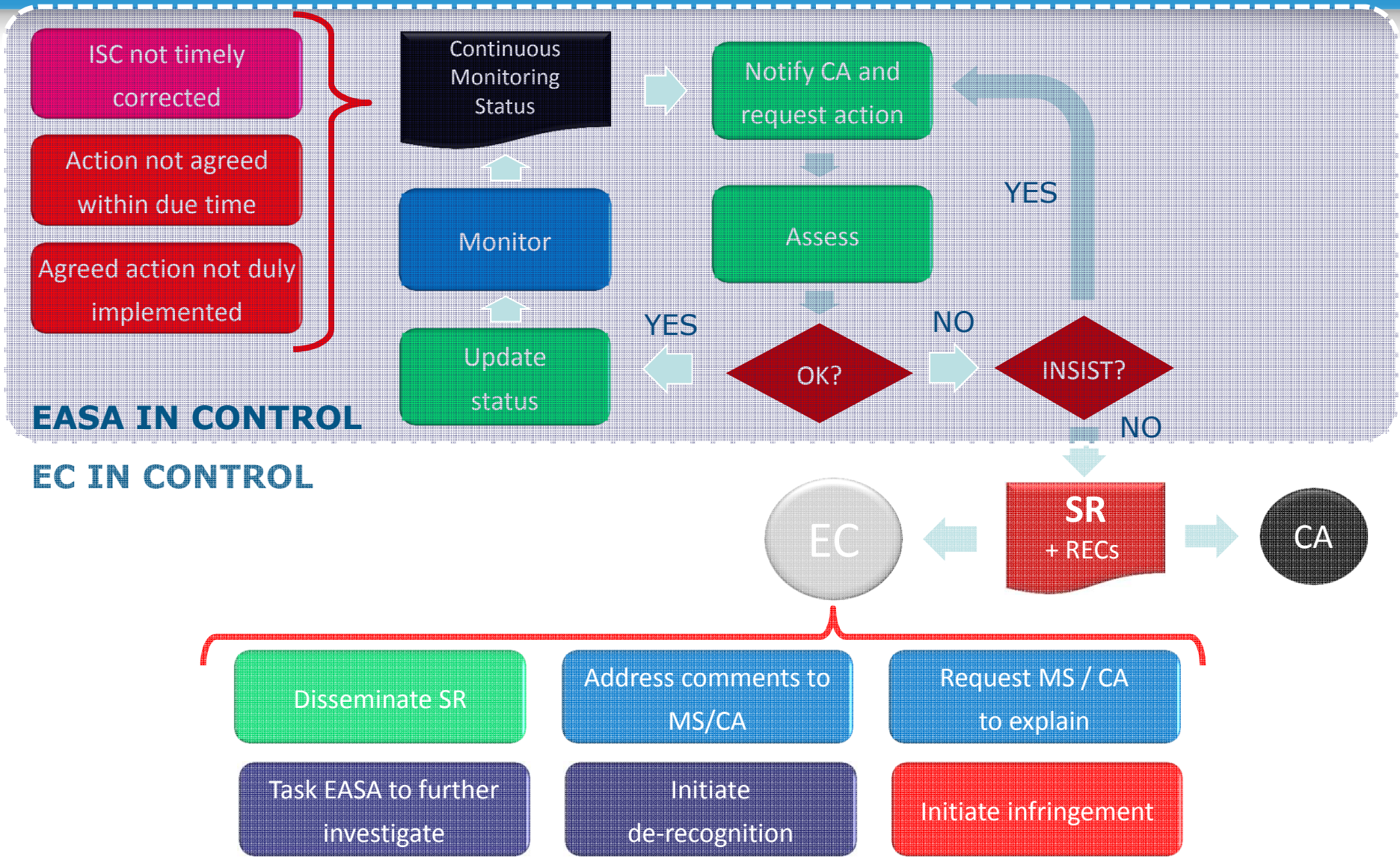


* For **(G)** findings, **immediate corrections** are required.

Internal EASA procedure says:

- CAP (D) & (G) immediately analysed and processed
- TL to keep agreement time as short as possible.

In case of disagreement?



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Thank you

Questions?

In case of doubts, please refer to the Mutual Expectation Paper

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