# 145.A.95 Findings and observations

Presentatör

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# 145.A.95 Findings and observations

Det ena "förbättringsverktyget" i Part-145



## Innehåll

- Grundförordningen
- 145.A.95 Findings and observations
  - Regel/AMC/GM
- Två försök att visualisera
- Summering



# Grundförordningen

(EU) 2018/1139

BILAGA II

### Grundläggande krav för luftvärdighet

- 3. ORGANISATIONER (INKLUSIVE FYSISKA PERSONER SOM UTFÖR KONSTRUKTION, PRODUKTION ELLER UNDERHÅLL ELLER HANTERING SOM SYFTAR TILL FORTSATT LUFTVÄRDIGHET)
  - 3.1 **Organisationsgodkännanden måste**, alltefter typen av verksamhet, utfärdas när följande villkor är uppfyllda:
    - b) <u>Organisationen</u> måste, alltefter vilken typ av verksamhet som bedrivs och organisationens storlek, införa och upprätthålla ett **ledningssystem** som säkerställer överensstämmelse med de grundläggande krav som fastställs i denna bilaga, hantera säkerhetsrisker <u>och</u> sträva efter en kontinuerlig förbättring av systemet.



## 145.A.95 Findings and observations

Regulation (EU) 2021/1963

- (a) After the receipt of a notification of findings in accordance with point 145.B.350, the organisation shall:
  - (1) identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
  - (2) define a corrective action plan;
  - (3) demonstrate the implementation of **corrective action** to the satisfaction of the competent authority.
- (b) The **actions** referred to in point (a) **shall be performed within the period agreed** with that competent authority in accordance with point 145.B.350.
- (c) The **observations** received in accordance with point 145.B.350(f) shall be given due consideration by the organisation. The organisation **shall record the decisions** taken in respect of those observations.

## AMC1 145.A.95 Findings and observations

ED Decision 2022/011/R

#### FINDING-RELATED CORRECTIVE ACTION PLAN AND IMPLEMENTATION

After receiving the notification of findings, the organisation should **identify** and **define the actions** for all findings to address the effects of the **non-compliance** and its **root cause(s)** and **contributing factor(s)**. Depending on the issues, the organisation may need to take **immediate corrections**.

### The corrective action plan should:

- include the correction of the issue, corrective actions and preventive actions, as well as the planning to implement these actions;
- be **timely submitted** to the competent authority for acceptance **before it is effectively implemented**.

After receiving the acceptance of the **corrective action plan** from the competent authority, the organisation should implement the **associated actions**.

Within the agreed period, the organisation should inform the competent authority that the **corrective** action plan <u>has been completed</u> and should send the **associated evidence**, as requested by the competent authority.



# GM1 145.A.95 Findings and observations

ED Decision 2022/011/R

#### **ROOT CAUSE ANALYSIS**

- (a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (regulatory, technical, human factors, organisational factors, etc.) in addition to the direct factors.
- (b) A narrow focus on single events or failures, <u>or</u> the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the **non-compliance**, <u>may not properly reflect the complexity of the issue</u>, and therefore there is a risk that important factors that must be addressed in order to prevent a reoccurrence will be ignored.
  - Such an inappropriate or partial root cause analysis often leads to defining 'quick fixes' that only address the symptoms of the non-conformity. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

## AMC2 145.A.95 Findings and observations

ED Decision 2022/011/R

### **DUE CONSIDERATION TO OBSERVATIONS**

For each observation notified by the competent authority, the organisation should **analyse** the related issues and determine when actions are needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

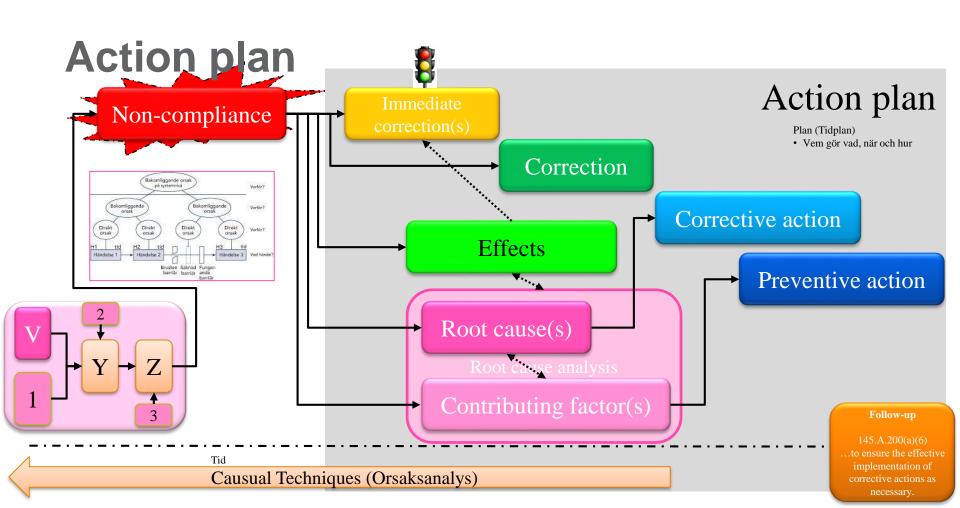
The organisation should <u>record</u> the **analysis and the outputs**, such as the actions taken <u>or</u> **the reasons for not taking actions**.

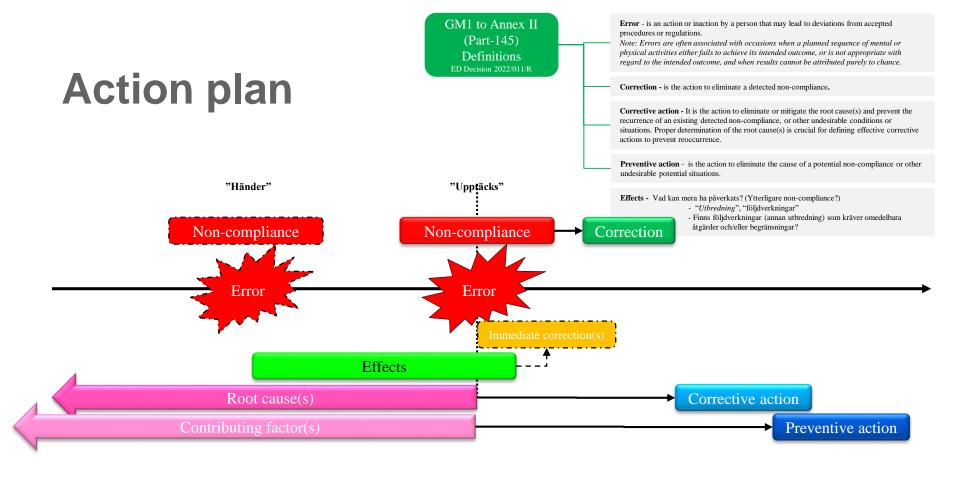


## Två försök att visualisera

Relationen mellan de olika åtgärderna









# Summering

- Grundförordningen
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## Det är inte bara vid avvikelser från TS

### AMC1 145.A.200(a)(3) Management system

ED Decision 2022/011/R

#### SAFETY MANAGEMENT KEY PROCESSES

### (c) Internal investigation

- (1) In line with its just culture policy, the organisation should define how to investigate incidents such as errors or near misses, in order to understand not only what happened, but also how it happened, to prevent or reduce the probability and/or consequence of future recurrences (refer to AMC1 145.A.202). This approach should avoid concentrating the analysis on who was (were) directly or indirectly concerned by the events.
- (2) The scope of internal investigations should extend beyond the scope of the occurrences required to be reported to the competent authority in accordance with point 145.A.60, to include the reports referred to in 145.A.202(b).