

21.A.158 Findings and observations

Presentatör

Johan Brunnberg

Flygteknisk Inspektör
Sjö- och luftfartsavdelningen
Enheten för operatörer, fartyg och luftfartyg
Sektionen för teknisk operation

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21.A.158 Findings and observations

Det ena "förbättringsverktyget" i Part-21 Subpart G

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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) **Organisationen 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 och **sträva efter en kontinuerlig förbättring av systemet.**

21.A.158 Findings and observations

Regulation (EU) 2022/201

- (a) After receipt of the notification of findings in accordance with point 21.B.225, **the holder of the production organisation approval certificate 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 the **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 21.B.225.
- (c) The **observations** received in accordance with 21.B.225(e) shall be given due consideration by the holder of the production organisation approval certificate. The organisation **shall record the decisions taken in respect of those observations.**

AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

ED Decision 2022/021/R

FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should **identify** and define the action for all findings, to address the **effects** of the **non-compliance**, as well as its **root cause(s)** and **contributing factor(s)**.

Depending on the issues identified, the organisation may need to take **immediate corrective action**.

The **corrective action plan** should:

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

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

Within the agreed period, the organisation should inform the competent authority that the **corrective action plan** has been implemented and should send the **associated pieces of evidence**, on request from the competent authority.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

ED Decision 2022/021/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)** of **non-compliance** often requires an overarching view of the events and circumstances that led to it, **to identify all the possible systemic and contributing factors** (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.
- (b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the **non-compliance**, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.
- Such an inappropriate or partial root cause analysis** often leads to applying 'quick fixes' that only address the symptoms of the **non-compliance**. A peer review of the results of the **root cause analysis** may increase its reliability and objectivity.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c) Findings and observations

ED Decision 2022/021/R

DUE CONSIDERATION TO OBSERVATIONS

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

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

The organisation should record the **analysis and the related outputs**, such as action taken, or **the reasons why no action was taken.**

Två försök att visualisera

Relationen mellan de olika åtgärderna

Action plan

Action plan

Plan (Tidplan)

- Vem gör vad, när och hur

Non-compliance

Immediate corrective action

Correction

Corrective action

Preventive action

Effects

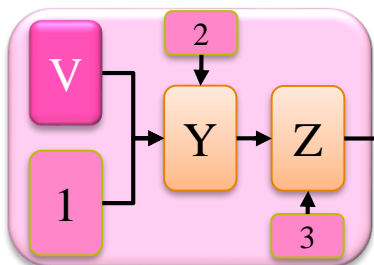
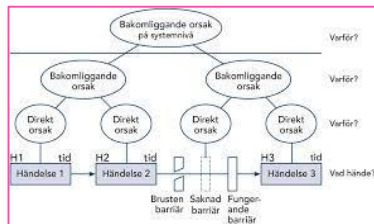
Root cause(s)

Root cause analysis

Contributing factor(s)

Follow-up

21.A.139(e)
...to ensure, where necessary, the implementation of corrective action.



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Causal Techniques (Orsaksanalys)



Action plan

GM1 Annex I Definitions

ED Decision 2022/021/R

Error - It is a person's action or inaction that may lead to deviations from the accepted procedures or regulations.
Note: errors are often associated with occasions when a planned sequence of mental or physical activities either fails to achieve its intended outcome, or is not appropriate with regard to the intended outcome, and when results cannot be attributed purely to chance..

Correction - It is the action to eliminate detected non-compliance..

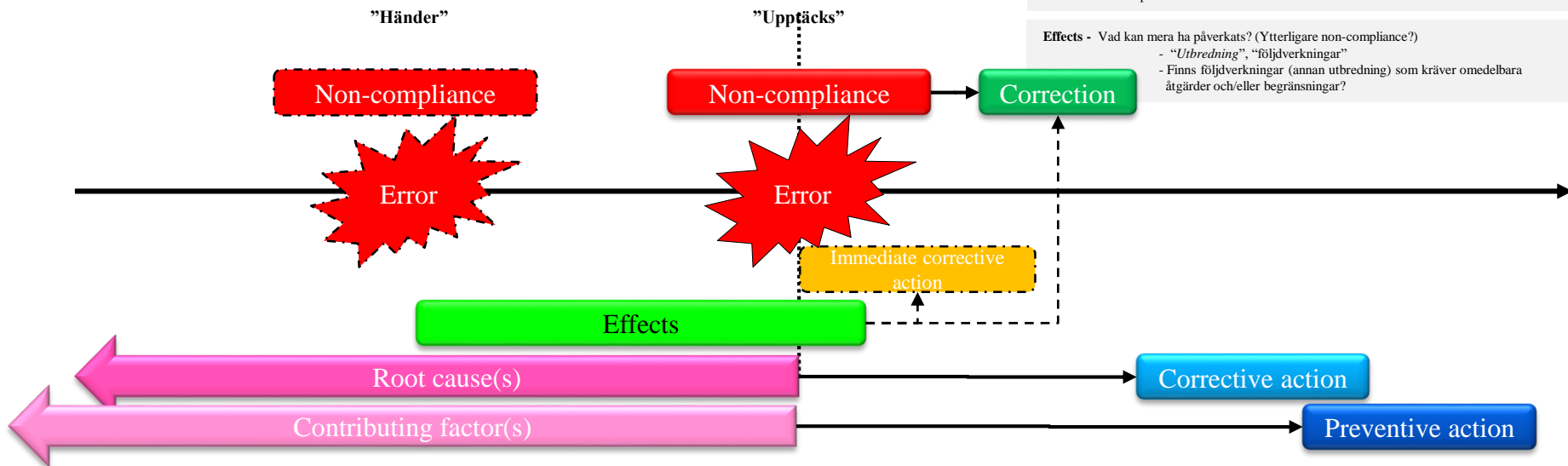
Corrective action - It is the action to eliminate or mitigate the root cause(s) and prevent the recurrence of existing detected non-compliance, or of any other undesirable condition or situation. Proper determination of the root cause(s) is crucial for defining effective corrective action to prevent recurrence.

Preventive action - It is the action to eliminate the cause of potential non-compliance, or any other undesirable potential situation.

Effects - Vad kan mera ha påverkats? (Ytterligare non-compliance?)

- "Utbredning", "Följdverkningar"

- Finns följdverkningar (annan utbredning) som kräver omedelbara åtgärder och/eller begränsningar?



Summering

- Grundförordningen
- 21.A.158
 - Regel/AMC/GM
- Två försök att visualisera

Det är inte bara vid avvikelser från TS

AMC1 21.A.139(c)(3) and (4) Production management system

ED Decision 2022/021/R

SAFETY MANAGEMENT KEY PROCESSES

(d) Internal investigation

- (1) In line with 'just culture' as part of the safety policy, the organisation should **define how to investigate** events such as **errors** or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.
- (2) The scope of **internal investigations should extend beyond the scope of the occurrences** that are required to be reported to the competent authority in accordance with point [21.A.3A](#).

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