

# Ledningssystem

Presentatör

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# Innehåll

- Production Management System - Introduktion
  - Från Quality System (QS) till PMS (MS)
  - Grundläggande principer
  - Förväntningarna – ”Beyond compliance”
- EU Management System
  - PO, 145, CAMO likheter/skillnader
- Integrerade ledningssystem och gemensamma handböcker

# Production Management System

Introduktion – bakgrund

# Innehåll

## Production Management System (PMS) - introduktion

- Från Quality System (QS) till PMS (MS)
- Grundläggande principer
- Förväntningarna – ”*Beyond compliance*”

# Från QS till PMS (MS)

# Quality System (QS) vs Management System (MS)

## M.G (145, 147) Organisations

### QS

- Compliance Monitoring (CMF)
- Procedurer för CAM, AR, PtF (MM, TM)

CMF – Compliance Monitoring Function

DAS – Design Assurance System

ISM – Independent System Monitoring

IQAF – Independent Quality Assurance Function

SMF – Safety Management Function

SMP – Safety Management Processes

AR – Airworthiness Review

CAM – Continuing Airworthiness Management

MM – Maintenance Management

TM – Training Management

PtF – Permit to Fly

## CAMO // 145

### MS:

- Responsibility (AM-CAM-SM-CMM)
- Safety policy & objectives
- SMF (SMP)
- Trained & competent personnel
- MS documentation (CAME // MOE)
- CMF
- CAM, AR, PtF // MM

## Production Organisation (21.G)

### QS:

- PM (*Production Management*)
  - *i-xvii*
- IQAF (CMF)

## Design Organisation (21.J)

### DAS:

- DM (*Design Management*)
- ISM (CMF)

## Ledningssystem för kvalitet – Krav (ISO 9001:2015)

4.4 Kvalitetsledningssystemet och dess processer

Organisationen ska bestämma vilka processer som behövs för kvalitetsledningssystemet och hur de ska tillämpas inom hela organisationen, och den ska:

- a) **bestämma nödvändiga underlag och förväntade resultat för dessa processer;**
- b) bestämma ordningsföljd för, och samverkan mellan, dessa processer;
- c) bestämma och tillämpa de kriterier och metoder (inklusive **övervakning, mätning** och tillhörande **nyckeltal**) som behövs för att säkerställa en verkningsfull tillämpning och styrning av dessa processer;
- d) bestämma vilka **resurser** som behövs för dessa processer och säkerställa att dessa resurser är tillgängliga;
- e) tilldela **ansvar och befogenheter** för dessa processer;
- f) **hantera risker och möjligheter** som bestäms i enlighet med kraven i avsnitt 6.1;
- g) **utvärdera** dessa processer och genomföra de eventuella ändringar som behövs för att säkerställa att processerna ger avsedda resultat;
- h) **förbättra** processerna och kvalitetsledningssystemet.

### Kvalitet

~Uppfylla kundens krav,  
behov och förväntningar  
(ISO 9000/9001)

# Från ICAO 9859 SMM 3rd

## 9859\_SMM 3rd-2013-Amd0

and specifications; and

- c) quality principles, policies and practices are linked to the objectives of safety management.

The relationship between SMS and QMS leads to the complementary contributions of each system to the organization's safety and quality goals. A summary comparison of the two systems is

**Table 5-1. Summary comparison of QMS and SMS**

<i>QMS</i>	<i>SMS</i>
Quality	Safety
Quality assurance	Safety assurance
Quality control	Hazard identification and risk control
Quality culture	Safety culture
Compliance with requirements	Acceptable level of safety performance
Prescriptive	Performance-based
Standards and specifications	Organizational and human factors
Reactive > Proactive	Proactive > Predictive

# Från SS-EN ISO 9000:2015 (Sv)

## 3.3.4 kvalitetsledning

*ledning* (3.3.3) med avseende på *kvalitet* (3.6.2)

Anm. 1 till termpost: Kvalitetsledning kan innefatta att upprätta *processer* (3.4.1) för att nå dessa kvalitetsmål genom *planering* (3.3.6), *kvalitetsstyrning* (3.3.7) och *kvalitetsförbättring* (3.3.8).

## 3.3.5 planering del av kva processer

Anm. 1 till te

## 3.6.2 kvalitet

grad i vilken inneboende *egenskaper* (3.10.1) h

Anm. 1 till termpost: Termen "kvalitet" kan använd

Anm. 2 till termpost: "Inneboende" innebär, i motsa

## 3.6.4

### krav

behov eller förväntningar som är angivna, underförstådda eller obligatoriska

Anm. 1 till termpost: "Underförstådd" innebär att det är vanligt eller allmänt vedertaget att det berörda behovet eller förväntningen är underförstådd inom *organisationen* (3.2.1) och av *intressenter* (3.2.3).

Anm. 2 till termpost: Ett specificerat krav är ett krav som är angivet i t.ex. *dokumenterad information* (3.8.6).

Anm. 3 till termpost: Ett bestämningsord kan användas för att ange en specifik typ av krav, t.ex. krav avseende *produkt* (3.7.6), *kvalitetsledning* (3.3.4), *kund* (3.2.4) eller *kvalitet* (3.6.2).

Anm. 4 till termpost: Krav kan ställas av olika intressenter eller av organisationen.

Anm. 5 till termpost: För god *kundtillfredsställelse* (3.9.2) kan det vara nödvändigt att uppfylla förväntningar hos en kund även om dessa förväntningar varken är angivna, i allmänhet underförstådda eller obligatoriska.

Anm. 6 till termpost: Detta är en av de gemensamma termerna och definitionerna för ISO:s standarder för ledningssystem som anges i bilaga SL av Consolidated ISO Supplement till ISO/IEC Directives, Part 1. Den ursprungliga definitionen har ändrats genom tillägg av Anm. 3 till och med 5 till termpost.

## 3.6.5

### kvalitetskrav

*krav* (3.6.4) med avseende på *kvalitet* (3.6.2)

## 3.6.6

### lagstadgat krav

obligatoriskt *krav* (3.6.4) specificerat av ett lagstiftande organ

## 3.6.7

### krav i förordning eller i myndighetsföreskrift

obligatoriskt *krav* (3.6.4) specificerat av ett organ med mandat från ett lagstiftande organ



# Från SS

## Orientering

### 0.1 Allmänt

Att införa ett ledningssystem för kvalitet är ett strategiskt beslut inom en organisation, vilket kan bidra till att förbättra organisationens övergripande prestanda och skapa en bra grund för initiativ till hållbar utveckling.

De tänkbara fördelarna för en organisation med att införa ett ledningssystem för kvalitet baserat på denna standard är att:

- a) ständigt kunna erbjuda produkter och tjänster som uppfyller kundkrav och tillämpliga författningskrav;
- b) underlätta möjligheten att öka kundtillfredsställelsen;
- c) hantera risker och möjligheter kopplade till organisationens förutsättningar och mål;
- d) visa överensstämmelse med krav som specificerats i ledningssystemet för kvalitet.

Denna standard kan användas av interna och externa parter.

Avsikten med denna standard är inte att hävda behov av att:

- ha likformig uppbyggnad hos olika ledningssystem för kvalitet;
- anpassa dokumentation till avsnittsstrukturen i denna standard;
- använda den specifika terminologin i denna standard inom organisationen.

De krav på ledningssystem för kvalitet som anges i denna standard utgör komplement till krav på produkter och tjänster.

Denna standard tillämpar processinriktning, och som delar ingår PDCA-cykeln (Plan-Do-Check-Act) och riskbaserat tänkande.

Processinriktningen gör det möjligt för en organisation att identifiera och kartlägga sina processer och hur dessa samverkar.

PDCA-cykeln gör att en organisation kan försäkra sig om att dess processer har tillräckliga resurser och lämplig ledning, samt att förbättringsmöjligheter identifieras och tillvaratas.

Riskbaserat tänkande gör det möjligt för organisationen att identifiera faktorer som kan göra att dess processer eller dess ledningssystem för kvalitet avviker från planerat resultat. Det gör det också möjligt att införa förebyggande åtgärder för att minimera negativa effekter och att maximalt utnyttja möjligheter när sådana uppkommer (se avsnitt A.4).

Att ständigt uppfylla krav och möta framtida behov och förväntningar utgör en utmaning för varje organisation i en allt mer dynamisk och komplex omvärld. För att uppnå detta mål kan organisationen kanske anse det nödvändigt att, utöver korrigerande och ständig förbättring, använda andra metoder såsom genomgripande förändringar, innovationer och omorganisationer.

# Grundläggande principer – PMS (& MS)

# 21.A.139 Production management system

(a) The production organisation shall establish, implement and maintain a **production management system** that includes a **safety management element** and a **quality management element**, with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The **production management system** shall:

1. correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;
2. be **established, implemented** and **maintained** under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1).

## Safety Management Element

(c) As part of the **safety management element** of the production management system, the production organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;
2. appoint key safety personnel in accordance with point 21.A.145(c)(2);
3. establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;
4. establish, implement and maintain a safety assurance process that includes:
  - (i) the measurement and monitoring of the organisation's safety performance;
  - (ii) the management of changes in accordance with point 21.A.147;
  - (iii) the principles for the continuous improvement of the safety management element;
5. promote safety in the organisation through:
  - (i) training and education;
  - (ii) communication;
6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.

## Quality Management Element

(d) As part of the **quality management element** of the production management system, the production organisation shall:

1. ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, thus enabling the exercise of the privileges set out in point 21.A.163;
2. establish, implement and maintain, as appropriate, within the scope of the approval, control procedures for:
  - (i) document issue, approval or change;
  - (ii) vendor and subcontractor assessment audit and control;
  - (iii) verifying that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;
  - (iv) identification and traceability;
  - (v) manufacturing processes;
  - (vi) inspection and testing, including production flight tests;
  - (vii) the calibration of tools, jigs, and test equipment;
  - (viii) non-conforming item control;
  - (ix) airworthiness coordination with the applicant for, or holder of, the design approval;
  - (x) the completion and retention of records;
  - (xi) the competence and qualifications of personnel;
  - (xii) the issue of airworthiness release documents;
  - (xiii) handling, storage and packing;
  - (xiv) internal quality audits and the resulting corrective actions;
  - (xv) work within the terms of approval performed at any location other than the approved facilities;
  - (xvi) work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
  - (xvii) the issue of a permit to fly and approval of the associated flight conditions;
3. include specific provisions in the control procedures for any critical parts.

## Independent Monitoring Function

(e) The production organisation shall establish, as part of the production management system, an **independent monitoring function** to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the production management system. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.

# Roller/funktioner

- AM och
- Nominated Managers

AM  
21.A.145(c)(1)

NM (SM(s))  
21.A.145(c)(2)

Safety  
Management  
Function

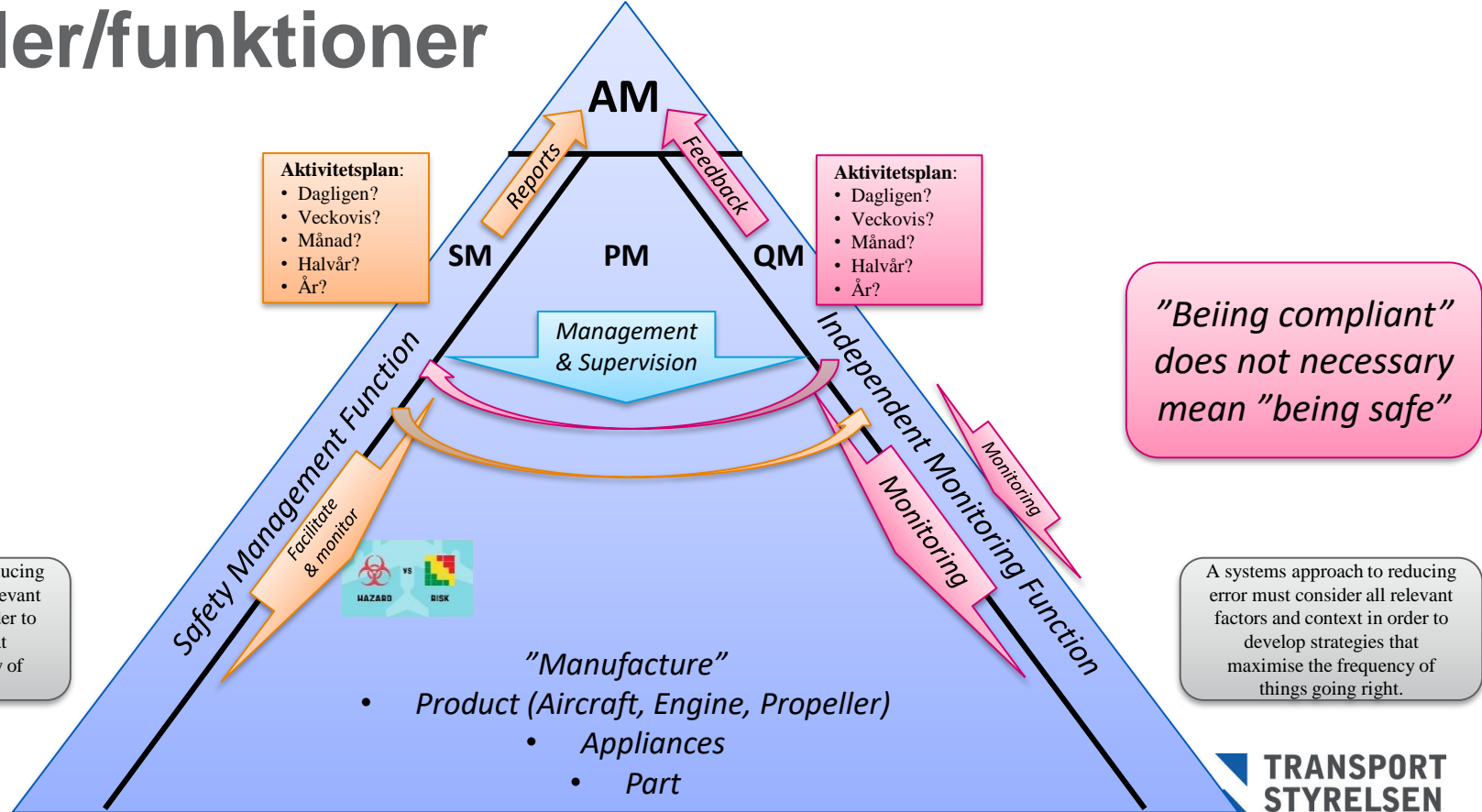
NM (PM(s))  
21.A.145(c)(2)

Manufacturing

NM (QM(s)) (CMM)  
21.A.145(c)(2)

Independent  
Monitoring  
Function

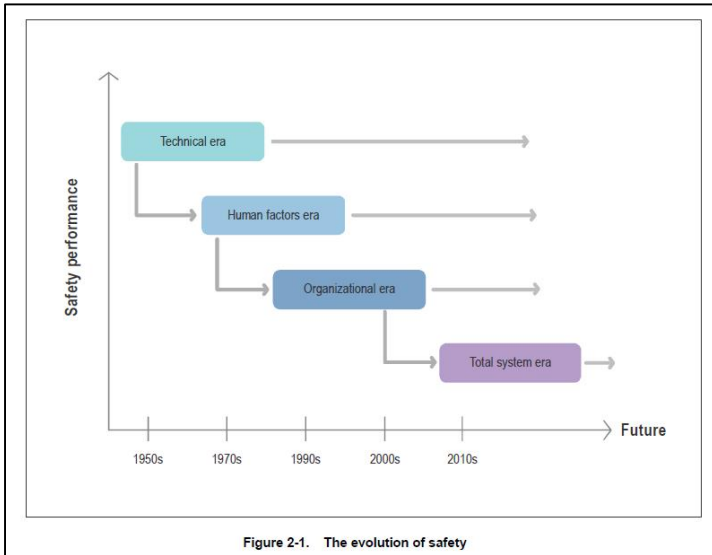
# Roller/funktioner



# Förväntningarna – ”Beyond” compliance

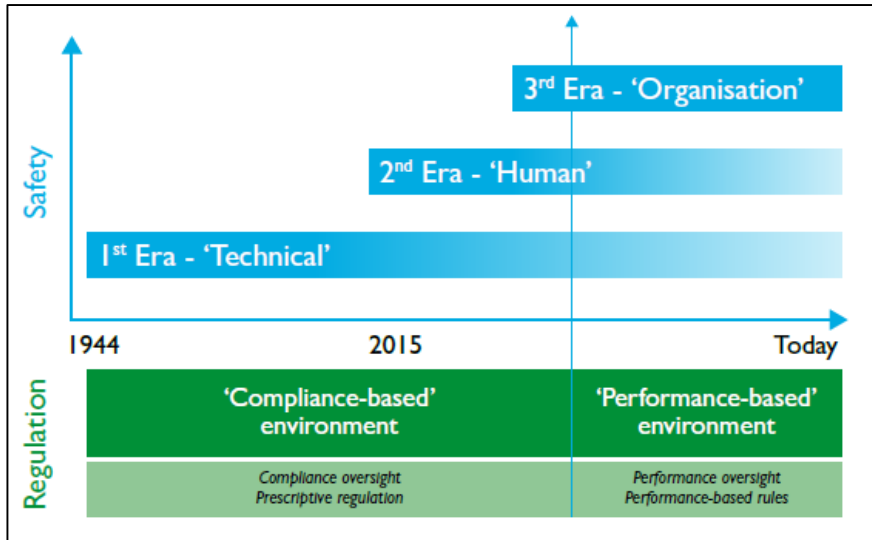
# Bakgrund

- Utvecklingen går framåt
- Från ”*compliance*” till ”*performance*”



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- Utvecklingen går framåt
- Från ”*compliance*” till ”*performance*”





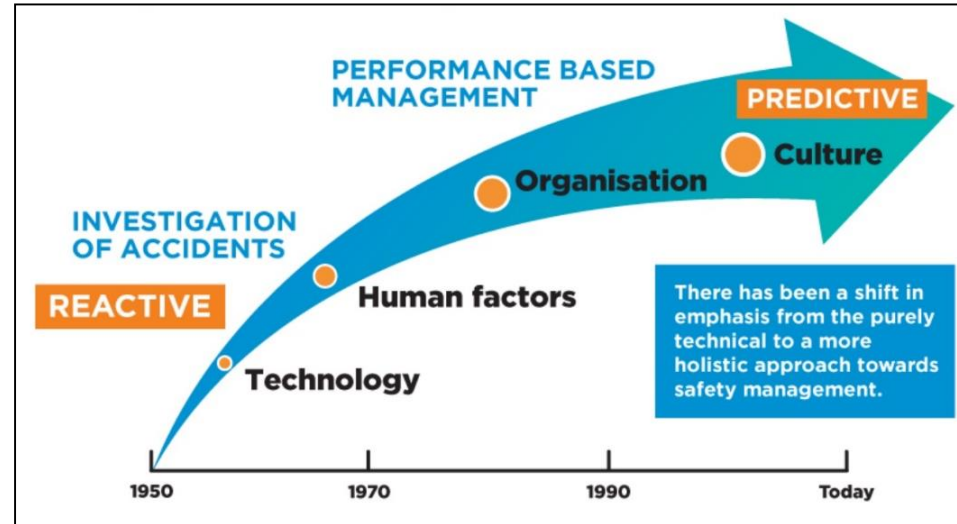
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- Utvecklingen går framåt
- Från ”*compliance*” till ”*performance*”



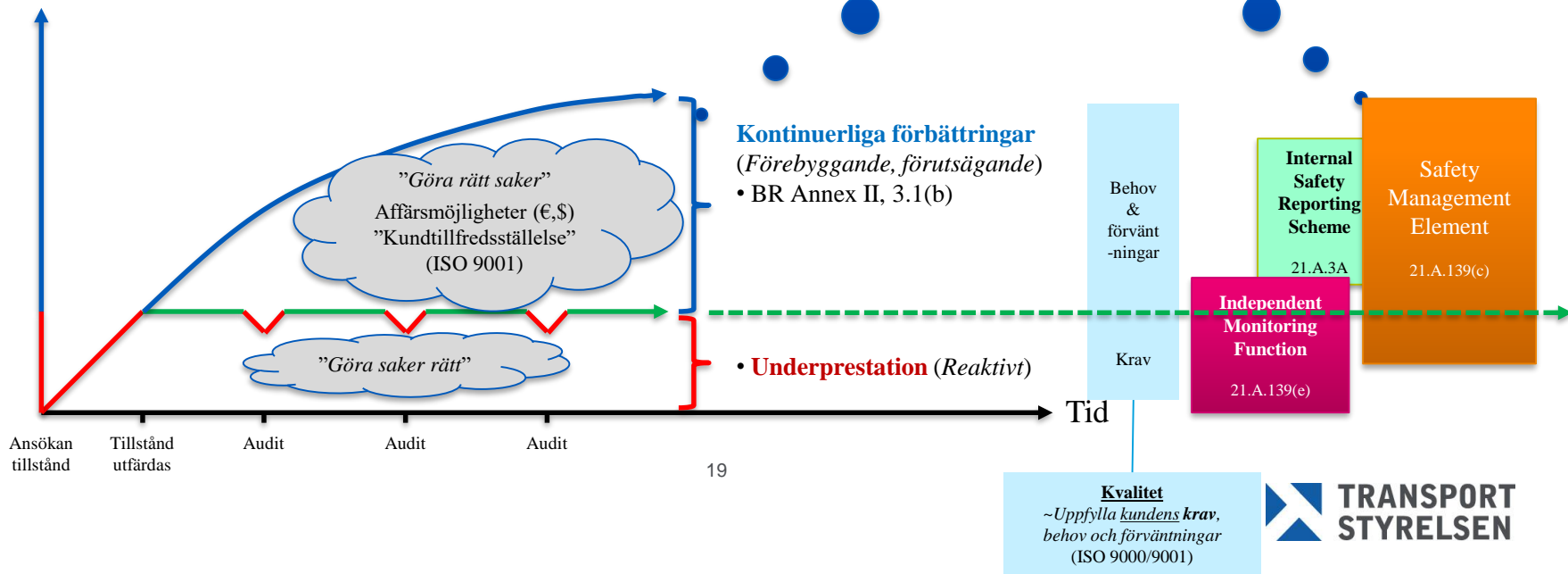
# Bakgrund

- Utvecklingen går framåt
- Från ”*compliance*” till ”*performance*”



# Förväntningarna

Säkerhets-  
prestanda  
(och regelbaserad  
Compliance)



# Från ”*compliance*” till ”*performance*”

## Bedömning av ”*performance*”

- Med fokus på:
  - Ledningssystemet (Management System)
    - Safety Management Element
      - Safety Risk Management  
**Förmågan** att identifiera faror med tillhörande åtgärder
    - Independent Monitoring Function
      - **Förmågan** att identifiera avvikelser med tillhörande åtgärder
- Bedömning av *ledningssystemets mognadsnivå* enligt
  - **P/S/O/E** - Present/Suitable/Operating/Effective

# P/S/O/E

Från GM1 CAMO.B.300(a);(b);(c) Oversight principles: (Finns inte i Del-21 ... än...)

ED Decision 2022/017/R

## MANAGEMENT SYSTEM MATURITY LEVELS

Regarding the evaluation of the maturity of the management systems, the following definitions apply:

- 'present'**: there is evidence that the process/feature is documented in the organisation's management system/safety management system (SMS) documentation;
- 'suitable'**: the process/feature is suitable based on the size, nature, and complexity of the organisation, and the inherent risk in the activity;
- 'operating'**: there is evidence that the process/feature is in use and an output is being produced;
- 'effective'**: there is evidence that the process/feature is achieving the desired outcome and has a positive safety impact.

EASA har utvecklat en modell för att bedömma detta för CAMO, MO (145), PO (21G) och DO (21J).

- **EMSAT**: *EASA Management System Assessment Tool*

# EU Management System

PO, 145, CAMO likheter/skillnader

# Innehåll

## Del 21 **PMS** / Del-145 **MS** / Del-CAMO **MS**

- Likheter/skillnader
- SMS vs PMS/MS
  - POA, 145, CAMO
- SMKP - Safety Management Key Processes
- ICAO vs EU

# SMS (ICAO Annex 19) till EU MS

## ICAO Annex 19

### APPENDIX 2. FRAMEWORK FOR A SAFETY MANAGEMENT SYSTEM (SMS)

#### 1. Safety policy and objectives

- 1.1 Management commitment and responsibility
- 1.2 Safety accountabilities
- 1.3 Appointment of key safety personnel
- 1.4 Coordination of emergency response planning
- 1.5 SMS documentation

#### 2. Safety risk management

- 2.1 Hazard identification
- 2.2 Safety risk assessment and mitigation

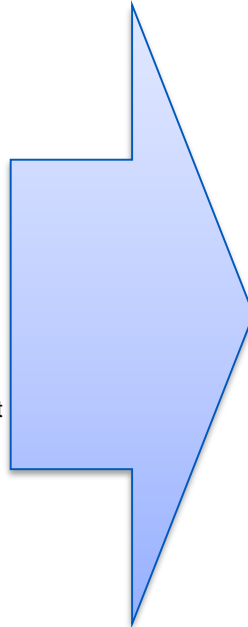
#### 3. Safety assurance

- 3.1 Safety performance monitoring and measurement
- 3.2 The management of change
- 3.3 Continuous improvement of the SMS

#### 4. Safety promotion

- 4.1 Training and education
- 4.2 Safety communication

- "Component" (4 st)
  - "Element" (12 st)



## EU Management System (21.G)

### 21.A.139 Production management system

- (a) The production organisation shall establish, implement and maintain a **production management system** that includes a **safety management element** and a **quality management element**, with clearly defined accountability and lines of responsibility throughout the organisation.
- (b) The **production management system** shall: ...
- (c) As part of the **safety management element** of the **production management system**, the production organisation shall:
1. establish, implement and maintain a **safety policy** and the corresponding related **safety objectives**;
  2. appoint key safety personnel in accordance with point 21.A.145(c)(2);
  3. establish, implement and maintain a **safety risk management** process to **identify safety hazards** entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;
  4. establish, implement and maintain a **safety assurance** process that includes:
    - (i) the measurement and monitoring of the organisation's safety performance;
    - (ii) the management of changes in accordance with point 21.A.147;
    - (iii) the principles for the continuous improvement of the **safety management element**;
  5. **promote safety** in the organisation through:
    - (i) **training and education**;
    - (ii) **communication**;
  6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.
- (d) As part of the **quality management element** of the **production management system**, the production organisation shall: ... 1, 2(i)-(xvii), 3.
- (e) The production organisation shall establish, as part of the **production management system**, an **independent monitoring function** to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the **production management system**. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.
- (f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the **production management system** may be integrated with that required under the additional certificate(s) held.

### 21.A.3A Reporting system

### 21.A.5 Record-keeping

### 21.A.145 Resources

### 21.A.147 Changes in the production management system

### 21.A.143 Production organisation exposition (POE)



# SMS (ICAO Annex 19) till EU MS

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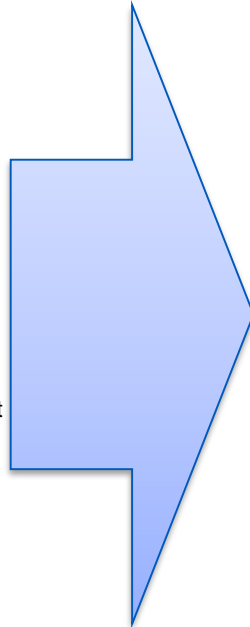
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- 3.3 Continuous improvement of the SMS

#### 4. Safety promotion

- 4.1 Training and education
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- **"Component"** (4 st)
  - "Element" (12 st)



## EU Management System (145)

### 145.A.200 Management system

- (a) The organisation shall **establish, implement and maintain** a management system **that includes**:
- (1) clearly defined accountability and lines of responsibility throughout the organisation, including a direct **safety accountability** of the accountable manager;
  - (2) a description of the overall philosophies and principles of the organisation with regard to safety ("**the safety policy**"), and the related **safety objectives**;
  - (3) the identification of **aviation safety hazards** entailed by the activities of the organisation, their evaluation and the **management of the associated risks**, including taking actions to **mitigate the risks** and verify **their effectiveness**;
  - (4) maintaining personnel **trained** and competent to perform their tasks;
  - (5) **documentation** of all management system **key processes**, including a process for making personnel aware of their responsibilities and the procedure for amending that documentation;
  - (6) a function to **monitor the compliance** of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure the effective implementation of corrective actions as necessary.

### 145.A.202 Internal safety reporting scheme

### 145.A.205 Contracting and subcontracting

### 145.A.30 Personnel requirements

### 145.A.60 Occurrence reporting

### 145.A.65 Record-keeping

### 145.A.70 Maintenance organisation exposition (MOE)

# SMS (ICAO Annex 19) till EU MS

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- 1.5 SMS documentation

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- 2.2 Safety risk assessment and mitigation

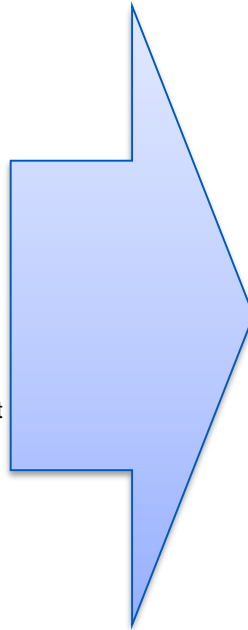
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- 3.3 Continuous improvement of the SMS

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- 4.1 Training and education
- 4.2 Safety communication

- **"Component"** (4 st)
  - "Element" (12 st)



## EU Management System (CAMO)

### CAMO.A.200 Management system

- (a) The organisation shall **establish, implement and maintain** a management system **that includes**:
- 1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct **safety accountability** of the accountable manager;
  - 2) a description of the overall philosophies and principles of the organisation with regard to **safety**, referred to as the **safety policy**;
  - 3) the identification of **aviation safety hazards** entailed by the activities of the organisation, their evaluation and the **management of associated risks**, including taking actions to **mitigate the risk** and **verify their effectiveness**;
  - 4) maintaining personnel **trained** and competent to perform their tasks;
  - 5) **documentation** of all management system **key processes**, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;
  - 6) a function to **monitor compliance** of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary;
  - 7) **any additional requirements** that are prescribed in this Regulation.

### CAMO.A.202 Internal safety reporting scheme

### CAMO.A.205 Contracting and subcontracting

### CAMO.A.160 Occurrence reporting

### CAMO.A.220 Record-keeping

### CAMO.A.300 CAME

### CAMO.A.305 Personnel requirements

# Lästips

## **GM1 21.A.139(c)** Production management system

- Part-145 och Part-CAMO har motsvarande.

## **AMC 21.A.139(c):** SM-0001\_issue B

EASA:

- [Safety Management & Promotion | EASA \(europa.eu\)](https://easa.europa.eu/safety-management-promotion)
- [Safety Promotion | EASA \(europa.eu\)](https://easa.europa.eu/safety-promotion)

Skybrary:

- [Safety Management | SKYbrary Aviation Safety](https://skybrary.com/safety-management)
- [SM ICG Safety Management Products | SKYbrary Aviation Safety](https://skybrary.com/safety-management-products)

# Håll isär

Management System

Safety Management Key Processes

Risk Management processes

# MS vs SMKP - POA

## EU Management System

### 21.A.139 Production management system

- (a) The production organisation shall establish, implement and maintain a **production management system** that includes a **safety management element** and a **quality management element**, with clearly defined accountability and lines of responsibility throughout the organisation.
- (b) The **production management system** shall: ...
- (c) As part of the **safety management element** of the **production management system**, the production organisation shall:
1. establish, implement and maintain a **safety policy** and the corresponding related **safety objectives**;
  2. appoint key safety personnel in accordance with point 21.A.145(c)(2);
  3. establish, implement and maintain a **safety risk management** process to **identify safety hazards** entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;
  4. establish, implement and maintain a **safety assurance** process that includes:
    - (i) the measurement and monitoring of the organisation's safety performance;
    - (ii) the management of changes in accordance with point 21.A.147;
    - (iii) the principles for the continuous improvement of the **safety management element**;
  5. **promote safety** in the organisation through:
    - (i) **training and education**;
    - (ii) **communication**;
  6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.
- (d) As part of the **quality management element** of the **production management system**, the production organisation shall: .... 1, 2(i)-(xvii), 3.
- (e) The production organisation shall establish, as part of the **production management system**, an **independent monitoring function** to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the **production management system**. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.
- (f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the **production management system** may be integrated with that required under the additional certificate(s) held.

## SMKP

### AMC1 21.A.139(c)(3) and (4)

#### SAFETY MANAGEMENT KEY PROCESSES

- a) Hazard identification processes
- b) Risk management processes
- c) *...hazard identification and risk management activities are performed on subcontracted activities...*
- d) Internal investigation
- e) Safety performance monitoring and measurement
- f) Management of change
- g) Continuous improvement

# MS vs SMKP - CAMO

## EU Management System

### CAMO.A.200 Management system

- (a) The organisation shall **establish, implement and maintain** a management system **that includes**:
- 1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct **safety accountability** of the accountable manager;
  - 2) a description of the overall philosophies and principles of the organisation with regard to **safety**, referred to as the **safety policy**;
  - 3) **the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness**;
  - 4) maintaining personnel **trained** and competent to perform their tasks;
  - 5) **documentation** of all management system **key processes**, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;
  - 6) a function to **monitor compliance** of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary;
  - 7) **any additional requirements** that are prescribed in this Regulation.

## SMKP

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

#### **SAFETY MANAGEMENT KEY PROCESSES**

- a) Hazard identification processes
- b) Risk management processes
- c) Internal investigation
- d) Safety performance monitoring and measurement
- e) Management of change
- f) Continuous improvement
- g) *Immediate safety action and coordination with the operator's Emergency Response Plan (ERP)*

# SMKP - SAFETY MANAGEMENT KEY PROCESSES - POA

## DOA

### Hazard identification processes

- Reactive & proactive methods
- ...**hazards** that may result from non-compliance or errors **in the design** of a product, part, or appliance.

- **Hazard identification processes**
  - Reactive & proactive methods
  - ...**hazards** that may generate nonconformity of a product, part, or appliance **that is produced**.
- **Risk management processes**
  - Analys
    - Probability/likelihood
    - Severity
  - Assessment Tolerability (Risk) (of occurrence/consequence)
  - Control/Mitigation
  - Tolerability (Authority to decide)
- **...hazard identification and risk management activities are performed on subcontracted activities...**
  - ...as well as for the monitoring of their compliance...
- **Internal investigation**
  - How to investigate (*How it happened*)
- **Safety performance monitoring and measurement**
  - Compare safety policy & safety objectives
  - SPI & SPT
- **Management of change**
  - Identify external and internal changes...
- **Continuous improvement**
  - Of Safety performance & effectiveness **PMS**

## CAMO/145

### Hazard identification processes

- Human Factors & Human Performance
- Organisational set-up

# ICAO vs

# EU

## ICAO Annex 19

### APPENDIX 2. FRAMEWORK FOR A SAFETY MANAGEMENT SYSTEM (SMS)

#### 1. Safety policy and objectives

- 1.1 Management commitment and responsibility
- 1.2 Safety accountabilities
- 1.3 Appointment of key safety personnel
- 1.4 Coordination of emergency response planning
- 1.5 SMS documentation

#### 2. Safety risk management

- 2.1 Hazard identification
- 2.2 Safety risk assessment and mitigation

#### 3. Safety assurance

- 3.1 Safety performance monitoring and measurement
- 3.2 The management of change
- 3.3 Continuous improvement of the SMS

#### 4. Safety promotion

- 4.1 Training and education
- 4.2 Safety communication



International Standards  
and Recommended Practices

Annex 19 to the Convention on International Civil Aviation

Safety Management

Second Edition, July 2016



Doc 9859

Safety Management Manual

Fourth Edition, 2016

## EU Management System

### CAMO.A.200

- (a) The organisation shall **establish, implement and maintain** a management system **that includes**:
- 1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct **safety accountability** of the accountable manager;
  - 2) a description of the overall philosophies and principles of the organisation with regard to **safety**, referred to as the **safety policy**;
  - 3) the identification of **aviation safety hazards** entailed by the activities of the organisation, their evaluation and the **management of associated risks**, including taking actions to **mitigate the risk** and **verify their effectiveness**;
  - 4) maintaining personnel **trained** and competent to perform their tasks;
  - 5) **documentation** of all management system **key processes**, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;
  - 6) a function to **monitor compliance** of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary;
  - 7) **any additional requirements** that are prescribed in this Regulation.

## SMKP

### AMC1 CAMO.A.200(a)(3) Management system SAFETY MANAGEMENT KEY PROCESSES

- a) Hazard identification processes
- b) Risk management processes
- c) Internal investigation
- d) Safety performance monitoring and measurement
- e) Management of change
- f) Continuous improvement
- g) Immediate safety action and coordination with the operator's Emergency Response Plan (ERP)

### • Risk management processes

- Analys
  - Probability
  - Severity
- Assessment Tolerability (Risk) (of occurrence/consequence)
- Control/Mitigation
- Tolerability (Authority to decide)



# Integrerat ledningssystem

# Möjlighet med integrerat ledningssystem

## 145

145.A.200

(c) If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the **management system** may be integrated with that required under the additional certificate(s) held.

## 21G

21.A.139

(f) If the **production** organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the **production management system** may be integrated with that required under the additional certificate(s) held.

Ja  
Men tänk på...

Hantering av  
handböckerna!

# Gemensamma handböcker

# Innehåll

## Möjligheten med gemensamma handböcker

- Krav:
  - GM1 145.A.200(a)(5) - AMC1 145.A.70(a)
  - GM1 21.A.143 - AMC1 21.A.143(a)(1) pkt (f)+(g)

# Att tänka på

- Revisionhanteringen internt
- Revisionhanteringen TS
- Att det framgår i POE att "xMM" är en del av POE'n (21.G)
- Att det framgår i "xMM" att "xMM" är en del av POE'n (21.G) och MOE (145)
- Vad som kräver "prior approval" kan vara olika mellan regelverken
- Att revisionsprocessen/proceduren tar hand om "båda" tillstånden
- Ändring - Ansökan kännedom/notifiering:
  - [TSL 7169](#)
  - ([operativt/CAMO](#))

# Önskemål från TS SloT (145) & SLoU (21.G)

- Fokusera på ett tillstånd i taget.
- Dvs – Den ”*gemensamma*” handboken (”xMM”) godkänd i ett tillstånd först.
- Sedan justera/revidera den ”*gemensamma*” handboken (”xMM”) för nästa tillstånd.
- Fokusera på ”**anpassningarna**”, för att underlätta granskningen och godkännandet för båda tillståndsområdena på TS.

# GM1 145.A.200(a)(5) Management system

ED Decision 2022/011/R

## MANAGEMENT SYSTEM DOCUMENTATION

(a) The organisation may document its safety policy, safety objectives and all its key management system processes in a separate manual (e.g. a Safety Management Manual or Management System Manual), or in its MOE (see AMC1 145.A.70(a), Part 3 'Management system procedures'). Organisations that hold multiple organisation certificates within the scope of Regulation (EU) 2018/1139 **may prefer to use a separate manual in order to avoid duplication**. That manual or the MOE, depending on the case, should be the key instrument for communicating the approach to the management system for the whole of the organisation.

(b) The organisation may also choose to document some of the information that is required to be documented in **separate documents (e.g. policy documents, procedures)**. In that case, **it should ensure that the manual or the MOE contains adequate references to any document that is kept separately. Any such documents are to be considered to be integral parts of the organisation's management system documentation.**

# GM1 21.A.143

## GENERAL

(a) The purpose of the production organisation exposition (POE) is to state in a concise documented format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation. The information to be provided is specified in point 21.A.143(a). Where this information is documented and integrated in manuals, procedures and instructions, the POE should provide a summary of the information and an appropriate cross-reference.

(b) Point 21.A.143(b) requires that the initial issued of the POE is approved by the competent authority. Revisions of the POE are subject to the process that is described in point (c) below.

(c) When changes to the organisation occur, according to point 21.A.143(c), the POE is required to be kept up to date. This should be done as per a procedure that is laid down in the POE. If the changes are significant, the organisation should not amend the POE before the competent authority approves the change in accordance with point 21.A.147.



# AMC1 21.A.143(a)(1)

## CONTENT OF THE PRODUCTION ORGANISATION EXPOSITION

(f) If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the POE and the other exposition. **In that case, the manual or supplement should identify where in the other exposition the remaining information on the production organisation (PO) is covered. That remaining information then formally becomes part of the exposition.**

(g) The organisation **may** document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.139(c)) **in a separate manual** (e.g. a safety management manual or management system manual) or in its POE. Organisations that hold multiple organisation approvals, which are issued under Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

# Summering

- Production Management System - Introduktion
  - Från Quality System (QS) till PMS (MS)
  - Grundläggande principer
  - Förväntningarna – ”Beyond compliance”
- EU Management System
  - PO, 145, CAMO likheter/skillnader
- Integrerade ledningssystem och gemensamma handböcker

# Ledningssystem

Presentatör

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Sektionen för teknisk operation

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