SMS NPA 2019-05

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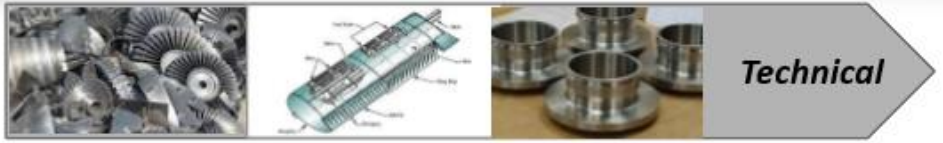
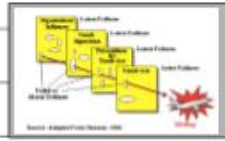


Technical

Better technology

Human

HF management, CRM, FRM etc...



Organisational

Quality Assurance, QMS
Threat & Error management

System safety

Safety management
SMS & SSP
addressing all of it :
better technology
Human & Organisational factors
compliance
risks
etc..

Global rate of accidents involving passenger fatalities per 100 million passenger miles, scheduled commercial air transport operations, excluding acts of unlawful interference

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Fast pace of technological change – new business models

Changing nature of accidents

- New types of hazards – emergence of **organisational accidents**

Reduced ability to learn from experience

- time to market for new products has greatly decreased

Increasing complexity and coupling of system 'components'

- cause and effect are less and less related in a direct/linear way

More complex relationships between humans and automation, role of software

Changing regulatory and public views (perception) on safety

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Hazard identification

- A method for identifying hazards related to the whole organisation (operational + systemic hazards)

Safety reporting

- A process for the acquisition of safety data not only related to product safety

Risk Management

- A standard approach for assessing risks and for applying risk controls

Performance Measurement

- Management tools for analysing how effectively the organisation's safety goals are being achieved

Safety Assurance

- Processes based on quality management principles that support continual improvement of the organisation's safety performance

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Annex 1
Personnel Licensing

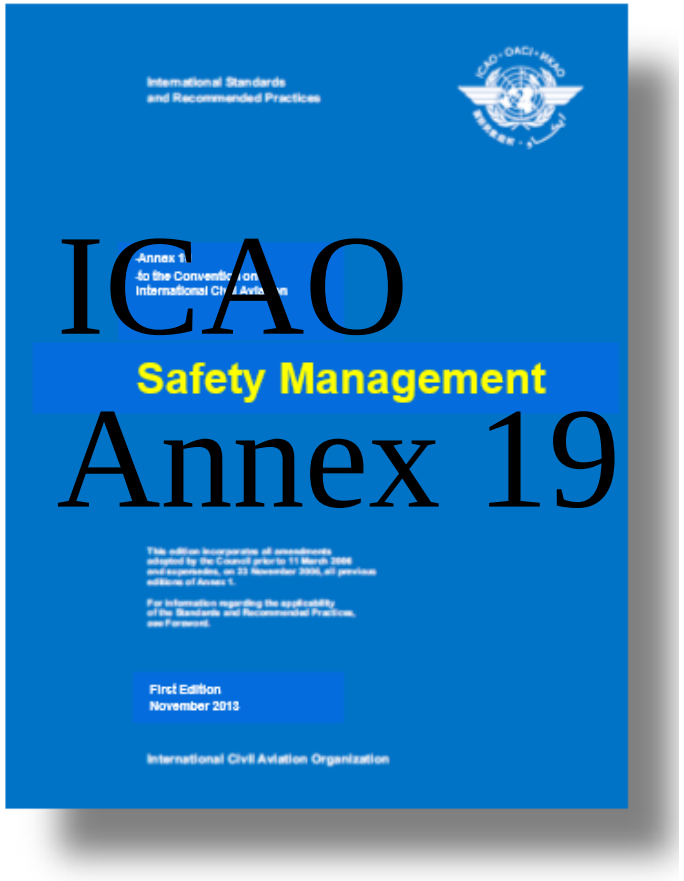
Annex 6
Operation of Aircraft

Annex 8
Airworthiness

Annex 11
Air Traffic Services

Annex 13
Aircraft Accident & Incident Investigation

Annex 14
Aerodromes



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EASA

- Authority Requirements (A/R) take due account of the critical elements of a safety oversight system defined by **ICAO Annex 19:**
  - implementation of the European Aviation Safety Programme (EASP).
- Organisation Requirements (O/R) include consolidated general requirements for management systems
- They are designed to embed the ICAO Annex 19 in a way as to ensure SMS compatibility with existing management systems and to encourage an integrated management system.
- **It should fit various organisations, whatever their size, nature or complexity** of activities and whatever business model they follow, thus catering for proportionate application.

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EASA

This NPA proposes to consider the applicability of safety management systems (SMSs) to Part-145 approved maintenance organisations, as well as to production and design organisations that are approved in accordance with Subparts G and J of Part 21.

- **NPA 2019-05** is divided into **three parts**.

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NPA 2019-05

NPA 2019-05 (A) includes:

- the procedural information pertaining to the regulatory proposal;
- the explanatory note to the proposed amendments;
- the regulatory impact assessment; and
- a detailed summary of the proposed amendments (see Chapter 7 ‘Appendices’).

NPA 2019-05 (B) proposes:

- the draft implementing rules (IRs) as well as the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) **for Part 21.**

NPA 2019-05 (C) proposes:

- the draft implementing rules (IRs) as well as the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) **for Part-145.**

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Vägen fram…

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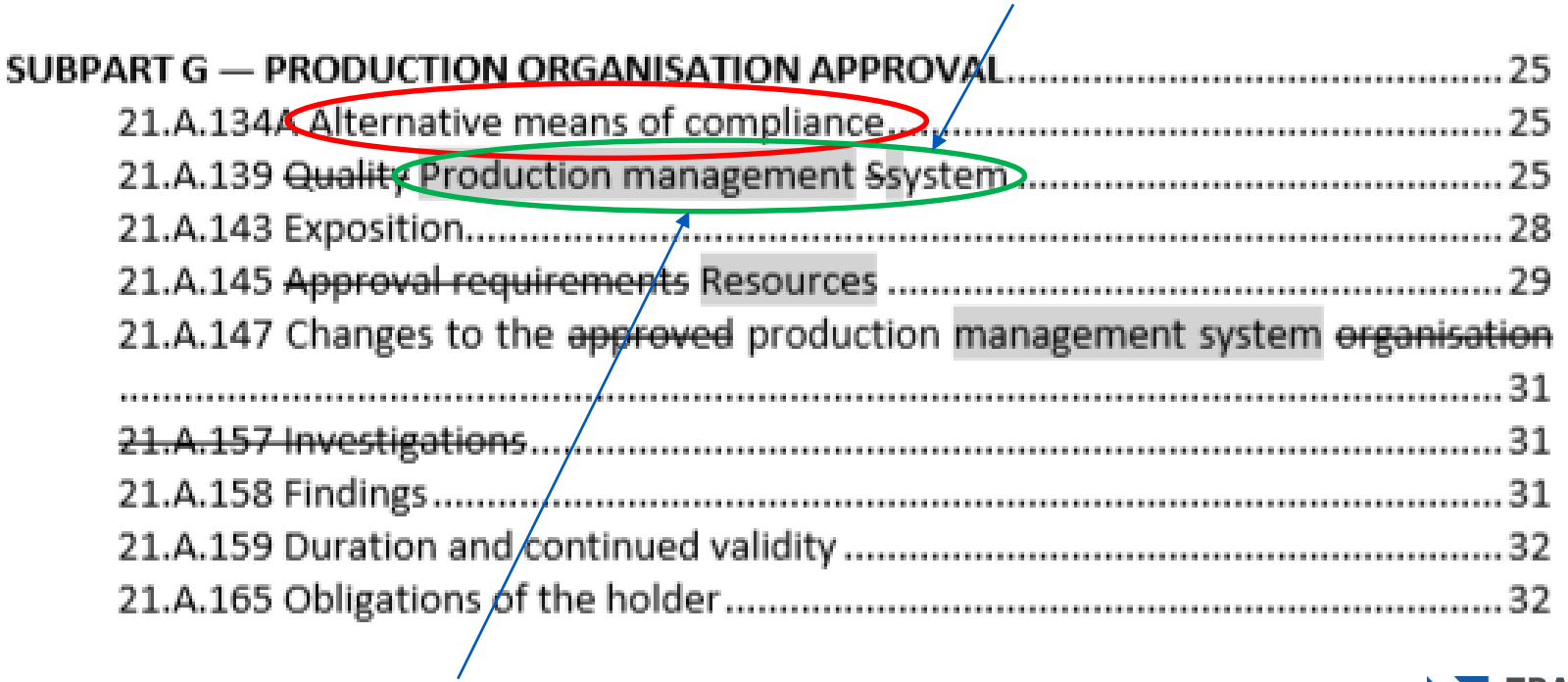
NPA 2019-05 (B)

139 a) – b) har blivit a) – g),
critical parts egen punkt ”3”



Including Quality system, Compliance monitoring

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NPA 2019-05 (B)

(EU) No 376/2014

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+ en massa AMC/GM..

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21.A.134A Alternative means of compliance

- (a) …
- (b) If an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the competent authority with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.

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AMC1 21.A.134A Alternative means of compliance

- (a) In order to demonstrate that the requirements are met, a risk assessment should be completed and documented. The result of this risk assessment should demonstrate that the alternative means of compliance reaches a level of safety that is acceptable to the competent authority.
- (b) The result of the risk assessment forms an integral part of the management system records to be managed in accordance with point 21.A.139.

AMC1 21.A.139(c)(1) Production management system

SAFETY POLICY & OBJECTIVES

(a) The safety policy should:

- (1) reflect **organisational commitments** regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;
- (2) include **internal reporting principles**, and encourage personnel to report production-related errors, incidents and hazards;
- (3) be **endorsed by the accountable manager**;
- (4) **be communicated**, with visible endorsement, throughout the organisation; and
- (5) be **periodically reviewed** to ensure that it remains relevant and appropriate to the organisation.

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AMC1 21.A.139(c)(1) Production management system

(b) The safety policy should include commitments to:

- (1) **comply with all the applicable legislation**, meet all the applicable requirements, and adopt practices that work towards improving safety standards;
- (2) provide the necessary **resources for its implementation**;
- (3) apply **human factors** principles;
- (4) enforce **safety as a primary responsibility of all managers**; and
- (5) apply **‘just culture’ principles,** and, in particular, to not make available or use any personal information on occurrences:

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AMC1 21.A.139(c)(1) Production management system

SAFETY MANAGEMENT ELEMENT — ORGANISATION AND ACCOUNTABILITIES

- (1) the **safety manager;** and
- (2) a high-level committee that considers matters of strategic safety, sometimes referred to as the '**safety review board**'

- (c) The accountable manager may also establish and maintain a function, referred to as the 'safety action group', in support of the **two functions** above.

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AMC1 21.A.139(c)(1) Production management system

- — If an organisation produces parts that have a limited effect on safety, it may limit the scope of its safety management system to cover only the areas that contribute to safety (e.g. the criticality will be different for the production of parts such as safety belts, or major elements such as an autopilot system).

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AMC1 21.A.139(c)(1) Production management system

- — The risks that are inherent in a complex structure require a robust safety risk management process (e.g. a complex supply chain may induce hazards that are complex to mitigate, or the rate of production, when stretched to the limit, will require more efficient safety barriers).

AMC1 21.A.139(c)(1) Production management system

- As a consequence, **scalability** should be a function of the inherent safety risk capability of the organisation. For instance:
- — the risk assessment model used may be very simple in small organisations where the identified hazards are easy to mitigate;
- — expert judgement might be sufficient to measure the efficiency of safety barriers;
- — the collection of data, safety information and occurrences might be very limited;
- — there might be no need for software and tools to manage the SMS;
- — the communication policy might be limited.

- **However, small organisations that are involved in activities that entail significant aviation safety risks might require greater SMS resources.**

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GM1 21.A.139(c)(4)(ii) Production management system

MANAGEMENT OF CHANGE

- Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. can result in the inadvertent introduction of new hazards, which can expose the organisation to new or greater risks.

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Exempel, Vägledning till ökad säkerhet i industriella informations och styrsystem - MSB

- **1** Säkra ledningens engagemang och ansvar för säkerheten i industriella informations och styrsystem.
- **2** Tydliggör roller och ansvar för säkerheten i industriella informations- och styrsystem.
- **3** …
- **4** Säkerställ en systematisk förändringshantering i industriella informations och styrsystem.
- **5** Säkerställ systematisk kontinuitetsplanering och incidenthantering i industriella informations- och styrsystem.
- **6** …
- **7** Möjliggör en god säkerhetskultur och höj medvetenheten om behovet av säkerhet i industriella informations- och styrsystem.
- **8-9** …
- **10** Genomför regelbundet riskanalyser av industriella informations- och styrsystem.
- **11-14** …
- **15** Genomför utbildning och övning av it-incidenter i industriella informationsoch styrsystem.
- **16** Följ upp incidenter i industriella informations- och styrsystem och bevaka säkerhetsproblem i omvärlden.
- **17** …

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Exempel på risker och problem

- I en organisation fanns det generella regler för hur medarbetare skulle agera med avseende på säkerhet.
- Efter en incident där ett USB-minne infekterat en dator i produktionsmiljön visade det sig att ledningen inte sett till att uppdatera styrdokumenten på över fyra år.
- Det fanns ingen utpekad ansvarig för att löpande genomföra relevanta riskanalyser och uppdatera riktlinjerna i styrande dokument för verksamheten.
- Ledningsgruppen hade inte heller formellt skrivit under styrdokumentet vilket medförde viss tveksamhet om riktlinjernas giltighet.
- I verksamheten rådde därför en kultur av att styrdokumenten inte behövde följas, eftersom ingen på chefsnivå verkade bry sig om, eller ens känna till reglerna. Exempelvis använde många chefer själva USB-minnen för att dela filer med varandra utan att reflektera kring de riktlinjer som fanns nedtecknade om just risker med USB-minnen.

Frågor – reflektioner?

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