EASA rules in the perspective of the “New Approach” for the safety of industrial products

Single European Sky Workshop
ETSI, Nice, 17 December 2008
Filippo Tomasello (EASA)
The Agency: main facts

- Independent legal status
- Operational since 2003
- Fees and charges regulation since 1st June 2005
- 400 staff
- More and more accepted as THE European aviation safety regulator
- Issuing opinions for the Community legislation
COMMISSION
• Adopts implementing rules
• Infringement procedures

Opinions
Reports
Comitology

Agency
• Works with States
• & stakeholders (SSCC)
• Proposes implementing rules
• Adopts AMCs, CSs, GM
• Standardisation
• Issues (rarely) certificates

AGNA
Inspections

STATES
• Assist Commission
• Advise EASA
• Issue (most) certificates
• Oversee organisations
Total system approach

EASA total aviation system approach

- Airworthiness
- OPS/FCL
- 3rd Country
- Aerodromes
- ATM/ANS

Economic regulation

Safety regulation

Performance regulation
European Aviation Safety Agency

Agency competencies

✈ Today:

🌟 Initial and continuing airworthiness (aircraft)
🌟 Air operations (operators)
🌟 Crew licensing (crew)
🌟 Authorisation for third country aircraft

✈ Tomorrow:

🌟 Aerodrome safety and interoperability
🌟 Air Traffic Management and Air Navigation Services safety
🌟 Environment
European Aviation Safety Agency

Proposed Changes to BR 216/2008


- New Annexes Va (aerodromes) & Vb (ATM/ANS)
- Scope Art. 1
- New definitions Art. 3
- Wider applicability Art. 4
- New articles
  - **Art. 8a, 8b, 8c, 8d**
  - **Art. 22a, 22b, 22c, 22d**
The Regulation applies to (....)

- Design, maintenance, operation & protection of surroundings of aerodromes, & personnel and organisations involved

- Design, production, maintenance of aerodrome equipment, & personnel and organisations involved

- Same for ATM/ANS systems, parts and appliances

- ATM/ANS (airspace use, services, personnel, organisations)
Certification of aerodromes - Art. 8a

Owner (or delegate) → Proposed CS + necessary changes → Application

Annex 14 + other docs → CSs

Competent Authority → Approved certification basis

Non legally binding

Approved certification basis → Legally binding

Verification of compliance → Certificate
Certification of aerodrome equipment - Art. 8a

† scope (i.e. which equipment it applies to) is to be defined in the IRs

† verification of compliance as part of the certification of the design

† safety critical equipment may be subject to dedicated certification schemes to be developed – possibly involving demonstration of capability of the designer / manufacturer

The model is the ETSO regime
European Aviation Safety Agency

“New approach” to technical harmonisation and standards

- **essential requirements** (ERs) by legislator
- **Implementing rules (IRs)** when necessary
- **Adoption of technical rules entrusted** to organisations with sufficient expertise and competence
- Community (or Certification) specifications **(CS)**
  - Not legally binding
- Possibility of **Acceptable/Alternative Means of Compliance (AMCs)**, instead of the CS, versus the ERs
- **Non duplication of conformity assessment**
- **Declaration of conformity**
- **Assessment by public authorities** when necessary

Council Resolution of 07 May 1985, modified by decision 768/2008:

**fundamental principles for the safety of products**

17 December 2008

ETSI SES Workshop 2008 - Nice

Filippo Tomasello
### European Aviation Safety Agency

**Does EASA comply with the “new approach”?**

<table>
<thead>
<tr>
<th>Principle</th>
<th>EASA</th>
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<tbody>
<tr>
<td>Only ERs in law for products</td>
<td>YES: ERs in Basic law</td>
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<tr>
<td></td>
<td>+ ERs also for services</td>
</tr>
<tr>
<td>Implementing rules</td>
<td>YES: B.R. 216/2008</td>
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<tr>
<td>CS not legally binding</td>
<td>YES/Explicit: Art. 15 Basic Reg.</td>
</tr>
<tr>
<td>AMC</td>
<td>YES: Art. 13 &amp; 15</td>
</tr>
<tr>
<td>Non duplication of conformity assessment</td>
<td><strong>Challenge in SES</strong></td>
</tr>
<tr>
<td>Declaration of conformity</td>
<td>YES: EASA “Form 1”</td>
</tr>
<tr>
<td>Assessment by authorities</td>
<td>YES: Certification</td>
</tr>
</tbody>
</table>

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The structure of the EASA rules

**ER’s (Essential Requirements)**

- **IRs** - Specific processes for design, production, ops & services
- **IRs (Q + S)**
- **IRs Authorities (AR)**

**AMCs** (one possible way to comply)

- For HW + SW

**CSs**

**GM** = explanations
### 4 streams of EU legislation

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<tbody>
<tr>
<td><strong>Scope</strong></td>
<td><strong>Safety of Products</strong></td>
<td></td>
<td></td>
<td>Safety of services</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td>Certificates of airworthiness for aircraft and engines</td>
<td>Conformity assessment + declaration of verification</td>
<td>Conformity assessment by notified bodies</td>
<td>SPECIFIC TO AVIATION (with SMS)</td>
</tr>
</tbody>
</table>
What are “Parts & appliances”?

Definition for the EASA Basic Regulation proposed by COM(2008) 390 final of 25 June 2008

- parts of an airframe, engine or propeller
- Any instrument, mechanism, part, apparatus, appurtenance, software or accessory for aerodromes or ATM/ANS systems
- equipment, including **aerodrome equipment**
- equipment used to manoeuvre the aircraft from the ground (e.g. **Ground Control Stations for UAS**)
- communications equipment, that is used or intended to be used in operating or controlling an aircraft in flight
- “**constituents**” as defined in Article 2, point (19) of Regulation (EC) No 549/2004
All Parts need approval

- **All parts** and their installation **need to be approved**
- Some parts, which can be « **separated** » from the « big » assembly (i.e. aircraft, engine, aerodrome or ATM system) can be **approved in isolation**
- In such a case **only their installation is verified during the certification** (or conformity assessment) of the « big » assembly (e.g. cables for antennas piercing a pressurized fuselage or power supply for an ILS transmitter)
- **The prior separate approval of the part (or equipment) simplifies the certification process and reduces liability of users**
Three possibilities for approval

- **in conjunction** with the certification of the “big” assembly [e.g. Type Certificate (or change to TC or STC) for aircraft] for parts which cannot be “separated” (e.g. fuel tanks integrated in the wing structure); **or**

- **Through European Technical Standard Order (ETSO); or**

- **By industry** for “Standard Parts” for which accepted standards exist (e.g. based on Directives for the “new” and “global” approach)

EASA has to decide when an **ETSO standard** is necessary: this also depends on existence of industry-wide standards
Is an ETSO standard necessary?

- **YES**
  - Apply industry standard
  - Assess conformity
  - **Label, mark or declaration** (always required by Part 21, Sub Q)
  - **Verify the correct installation, implementation on site**

- **NO**
  - EASA issues **ETSO**: Following the Rulemaking procedure
  - For **voluntary** application
  - Part approval
Why an ETSO standard may be necessary?

- To issue specification in the absence of industry standards (e.g. ETSO C26c on aircraft wheels and brakes)
- To give certainty on the applicability of a document by EUROCAE, RTCA, ETSI or SAE
- To complement, modify or establish exceptions w.r.t. industry standards (e.g. ETSO C9c on autopilots)
- For ATM/ANS systems/constituents and aerodrome equipment decisions will be taken case by case
- Applicable implementing rules may be different from Part 21
Content of ETSO

- **Minimum performance standards** developed by EASA, or
- Reference to existing & appropriate (aviation wide) industry standards (e.g. EUROCAE or SAE)
- Additional conditions if necessary

More solid and clearer basis for application of aviation standards
European Aviation Safety Agency

**ETSO NOT legally binding**

- **YES**
  - Request authorisation?
  - Apply ETSO?
  - NO
    - Compliance against equivalent specs
  - YES
    - Obtain AP-DOA
    - ETSOA
    - Approve minor design changes
    - Manufacturer signs “Form 1”
    - Verification of:
      - Additional functionality
      - Installation

- **NO**
  - Burden of proof
It is a finding that:

- Constitute separate approval for certain “parts” (pieces of equipment)
- covers both design (of the part) and production process (quality control)
- Article design meets a specific ETSO MPS
- Article produced under approved quality control system
- independent from “product” design (i.e. it can be installed in various aircraft or at different aerodromes/sites)
- production aspect: POA required
- No “full” DOA required (except for APU)

ETSOA are issued by EASA
The opinion of ASD

At SES Workshop in Köln 16 Oct 2008

- ATM market of small size
- Systems and constituents used almost exclusively for ATM purposes (not intended for the general public)
- Declaration of conformity sufficient for constituents
- This does not exclude Community Specifications or some form of approval of the manufacturer
- The transitional strategy needed
- Unjustified cost-benefit barriers to preservation of the existing infrastructure should be avoided
Families of ATM/ANS systems

1 - On board ATM systems subject to EASA procedures already applied to the other on board parts

2 - ATM/CNS ground systems. We could distinguish mainly three families of systems:
   a) - **CNS systems that will be produced in series**
   b) - Large and complex system integrating constituents (HW & SW) only in ONE individual: e.g. Area Control Centres
   c) Integrated Airport systems (e.g. TWR)

3 - **Satellite systems**: Large complex satellite navigation and communication systems (Galileo, Iris,...)
Clearly most of the infrastructure and ATM/ANS or aerodrome systems exist today.

The approach taken by EASA with respect to this is key to the overall cost.

It can be assumed that EASA will not demand the recertification of existing systems (already declared safe and suitable for use).

If such systems are upgraded, modifications shall comply with EASA rules a cost effective and flexible way.

EASA AMCs, CSs and ETSOs are flexible by definition!