EASA approach for assessing the 482/2008 compliance

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EASA Safety Oversight in ATM (I)

**Sources:**
- Legal basis in Art. 22a of Reg. 216/2008
- Implementing Rule 805/2011 on ATCO Licensing
- Implementing Rule 1034/2011 on Safety Oversight
- Implementing Rule 1035/2011 on Common Requirements for the provision of Air Navigation Services.

**EASA Responsibilities:**
- Standardisation Inspections of NSAs
- Safety Oversight of:
  - ANSP organisations located outside the EU
  - ANSP organisations providing Pan-European Air Navigation Services
  - ATOs for ATCOs located outside the EU

  » Note: “Pan-European ANS means a service which is designed and established for users **within most or all Member States** and which may also extend beyond the airspace of the territory to which the Treaty applies”

- Assisting the European Commission, Safety Oversight of the Network Manager.
Software Assurance related aspects are covered by Reg. 482/2008 for systems supporting the following types of services:

- Air Traffic Services (ATS)
- Air Traffic Flow Management (ATFM)
- Air Space Management (ASM)
- Communication, Navigation and Surveillance services (CNS)

Software Safety Assurance System (SSAS) shall be part of the Safety Management System.

The SSAS is subject of assessment by EASA for the organisations for which EASA is the Competent Authority.
Means of Compliance:
- EUROCAE ED12B/RTCA DO178B as Acceptable Means of Compliance (AMC 20-115B)
- Certification Review Items (CRI) for some particular issues/techniques (e.g., model based development, object oriented techniques), complementing it.

Key Principles:
- Organisation capability by holding a Design Organisation Approval.
- Compliance demonstration responsibility of the organisation.
- Authority verifies, by sampling, this compliance demonstration.

Methodology is based on four main milestones, performed as desktop reviews or as on-site audits (sampling):
- Planning Review, to confirm the compliance of the software plans (e.g., PSAC) w.r.t. ED12B/DO178B and agreed CRIs.
- Development Review, to assess the compliance of the software life cycle data, regarding development aspects (up to source code prod.).
- Verification Review, to assess the compliance of the software life cycle data, regarding verification aspects.
- Final Certification Review, to confirm the final compliance of the selected software item(s).
Approach also applied by other Authorities (e.g., FAA-US, TCCA-Canada, ENAC-Brazil).

A risk-based approach is used to identify the software item(s) and the depth of the assessment:

- Depending on several criteria (e.g., assurance level, novelties, supplier’s experience, level of changes), EASA defines the Level Of Involvement (LOI) for each of the software items:
  - **NONE**: no EASA assessment
  - **LOW**: only two desktop reviews (typically, Planning Review and Final Review)
  - **MEDIUM**: two desktop reviews plus one on-site audit (typically, combined Development/Verification Review)
  - **HIGH**: two desktop reviews plus two on-site audits (typically, Development and Verification Reviews)
When defining the assessment process for software aspects, the following aspects have been taken into account:

- Particular aspects of the Reg. 482/2008
- Particularities of the ATM software (e.g., legacy software, COTS)
- Software errors contribution to failure conditions (this effect is accounted through the assurance level allocation)

And also considering:

- Risk based approach for the oversight
- Relevance of the on-site audits (sampling) for assessment of the software compliance and associated processes (e.g., inspection of life cycle data)
- Relevance of the software planning documentation
Several cases:

- **Internal development** (all software is developed in-house by the Service Provider)
  - SSAS is only based on internal procedures.

- **External development/procurement** (no software is developed by the Service Provider),
  - SSAS is set up by the Service Provider (as part of its SMS) but relies partially or completely on plans and procedures from the equipment/software manufacturers.

**Combined situation**

When to assess the software aspects:

- As part of the **review of notified changes** (for changes where software is impacted)
- As part of the **SMS oversight**, regarding the changes notified/introduced by the Service Provider.

Case by case decision, depending on the development approach and the particular Service Provider set-up for the software activities.
Two types of activities:

- **Desktop reviews:**
  - Review of procedures/software planning documentation
  - Review of final certification software documents (e.g., SAS, SSF)

- **On-site audits (sampling):**
  - For selected software items (risk based approach)
  - EASA Involvement to be agreed with the Service Provider
  - Participation of the Service Provider in the on-site audits at supplier premises

Service Provider is informed about the selected approach (including a detailed identification of the activities) through a specific document named **Level Of Involvement**, delivered by EASA for each notified change to be reviewed.
Assessment of software aspects in ATM (IV)

- References for this assessment:
  - Regulation 482/2008
  - Means of Compliance agreed (ED12B/DO178B, ED109/DO278, ED-153, ...)
  - Service Provider procedures
  - Software suppliers planning documentation

- Comments/findings (if any) resulting from the desktop reviews/on-site audits (sampling) will be managed through the action plans (CAPs).
In order to exercise its responsibilities as Competent Authority, EASA has defined a software assessment approach for the compliance with Reg. 1035/2011 and Reg. 482/2008.

Relevance of the **on-site audits (sampling)** as instrument for compliance verification.

Sampling allows direct access to software life cycle data:
- Direct verification of compliance with Reg. 482/2008 (e.g., traceability, requirements validation)
- Confirmation that the plans/procedures are followed
- Assessment of the organisation quality assurance activities

Involvement to be defined and agreed with the service provider on a **risk-based approach**, taking into account:
- Software criticality (assurance level, SWAL)
- Software complexity
- Novelties (methods or technologies)
- Software development/organisation processes maturity
Thank you for your attention

Questions ?

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