



EASA
European Aviation Safety Agency

European Aero-Medical Certification Requirements

AME refresher training

Dr. Cristian Panait
Medical Expert

21 September 2018

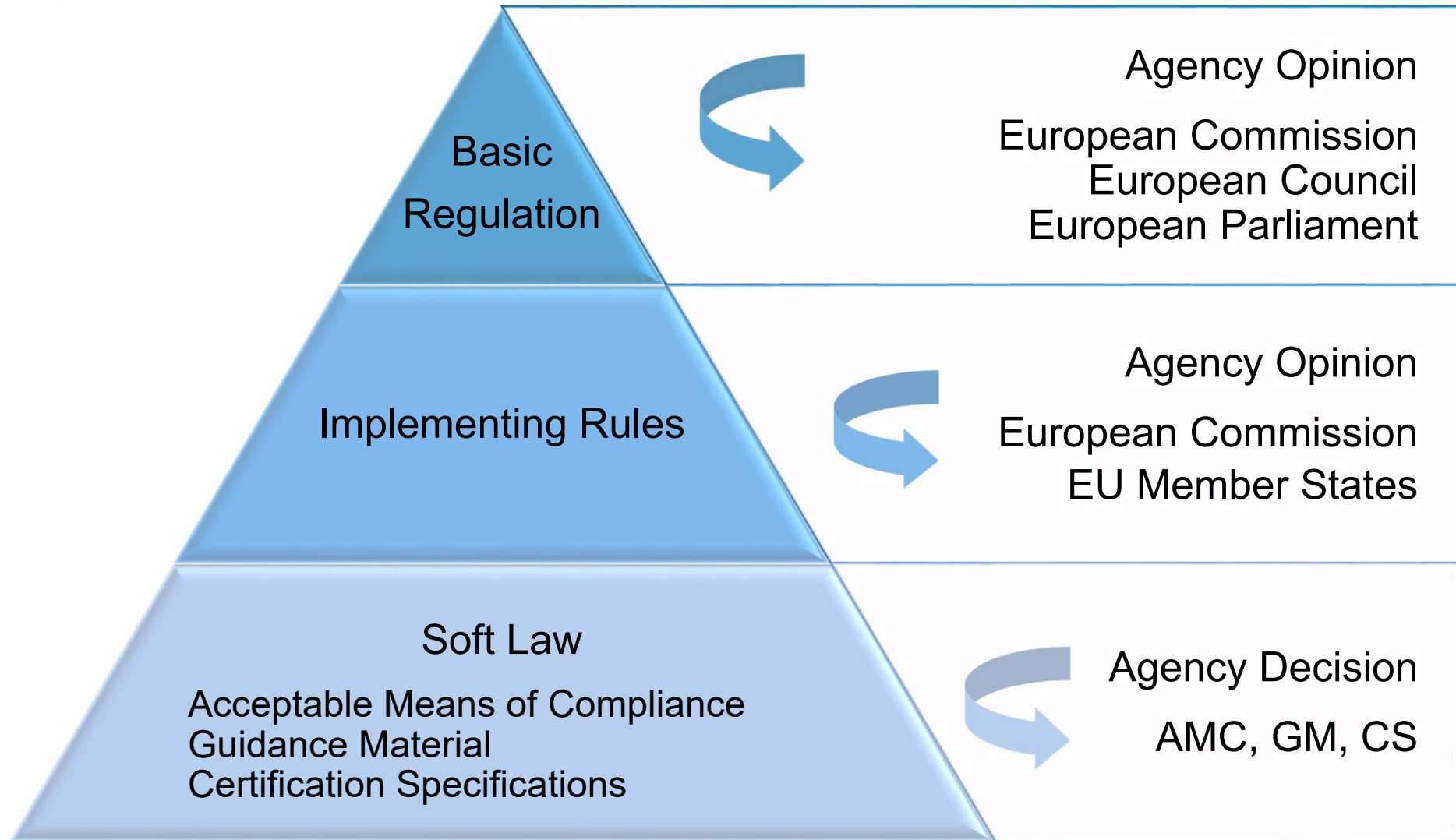
Your safety is our mission.

An agency of the European Union





Regulatory Structure





Current EASA Regulations

Basic Regulation (EC) No 216/2008

Airworthiness

Flight Standards

ATM/ANS

ADR

Initial
Airworthiness



Continuing
Airworthiness



Air Crew



Air
Operations



ANS
common
requirements



ATM/ANS
safety
oversight



ATCO
licensing



ADR
requirements



Airspace
usage
requirements



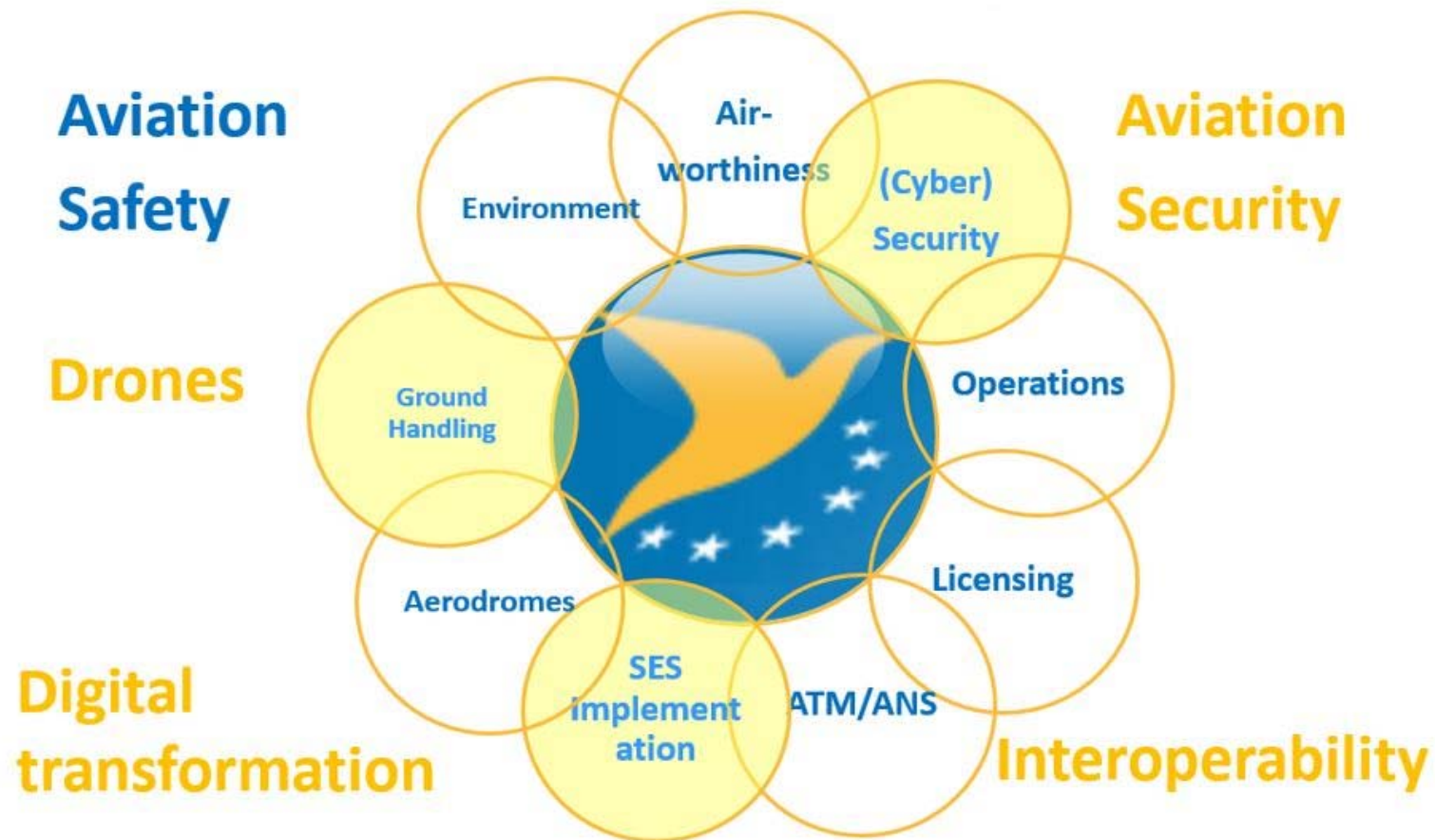
SERA





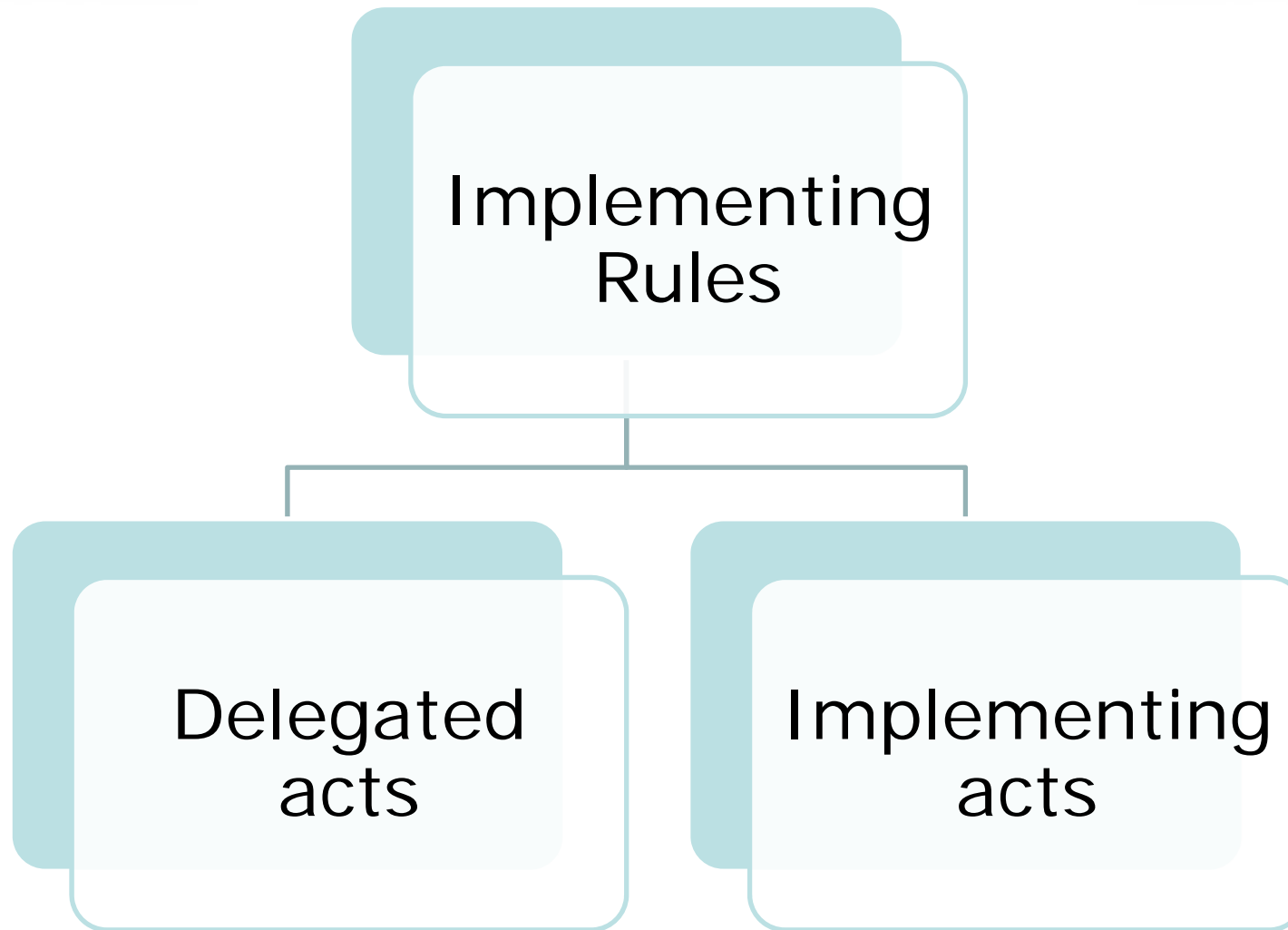
New Basic Regulation

'old' BR → NBR





Regulatory Structure - NBR





Roles EU aero-medical certification

- **Art.290-Delegated Acts:** The Commission has the power to adopt non-legislative acts of general application that supplement or amend certain non-essential elements of a legislative act.
 - Process: EASA Opinion – COM draft regulation; Consultation with MS experts; Inter-service consultation + 4-week feedback for MS; Adoption by EC-EP and Council can object.

- **Art.291-Implementing Acts:** Responsibility for implementing legally binding EU acts lies primarily with EU countries. However, some legally binding EU acts require uniform conditions for the implementation. In these cases, the Commission or the Council is empowered to adopt implementing acts. Always voted in the Committee.
 - Process: EASA Opinion – COM draft regulation; Consultation with MS experts; Inter-service consultation + 4-week feedback for MS; Draft IA – discussion and vote in Committee; Right of scrutiny – EP and Council; Adoption by EC.



The EU aero-medical certification process

- **PROFESSIONALISM, HONESTY AND TRUST**
- **Just Culture**
 - Not punishing individual mistakes, except mistakes performed with bad intentions
 - Analyzing mistakes and taking actions to prevent such mistakes from repeating
- AME main focus: **Keeping aeronautical personnel healthy** and fit to safely exercise the privileges of their licences
- **Health promotion:** Identifying the risk factors to prevent potentially career threatening medical problems



The EU aero-medical certification process

- **FLIGHT SAFETY AND A LONG, HEALTHY AND FULFILLING ACTIVITY** Top priorities for pilots, ATCOs or cabin crew
- **ENCOURAGE** the development of a trust culture between applicants and AMEs
- **WORK TOGETHER** towards the same goal: **Make an extensive and safe career in aviation**



Risk assessment

- **The risk assessment** should be a holistic process taking into consideration:
 - Applicant's social and working environment
 - Medical history
 - Comorbidities
 - Examination and investigations' results

- In case of doubt, **consultation** with the medical assessor of the applicants' licensing authority, your peers or other medical specialists



Rulemaking Task RMT.0287

- Scope of RMT.0287 - to update Part-MED, Part-ARA and Part ORA IR and related AMC and GM
- The Task was split in two parts:
 - (a) update of Part-MED and related AMC and GM;**
 - (b) update of medical relevant requirements in Part-ARA and Part-ORA
- Objective - to review Part-MED to correct any editorial errors, consistency issues or gaps identified through implementation experience



Part-MED NPA and CRD

- NPA 2013-15 'Update of Part-MED'
 - Published on 26 July 2013
 - 392 comments

- CRD 2013-15 'Update of Part-MED'
 - Published on 25 September 2014
 - 42 reactions to the CRD

- Following the Germanwings accident the EASA lead Germanwings Taskforce issued 6 recommendations to address the safety concerns

- Q1 2016 – decision to harmonise the draft Part-MED requirements with Germanwings Taskforce recommendation



Overview of Germanwings Taskforce Recommendations

RECOMMENDATIONS

		1	2	3	4	5	6
WP6 – Project Management	EASA						
	WP1 - Aircrew Medical Fitness Workshop		Psychol. Evaluation + Aeromed assessment AMEs Training	Drugs & alcohol test	AMEs oversight + networks	Aeromed data repository	Pilots report & support systems
	WP2 - Air operations	2-persons in cockpit	Psychol. evaluation	Drugs & alcohol operators			Pilots report & support systems
	WP3 - Aircrew		Aeromed assessment + AMEs training	Drugs & alcohol medical	AMEs oversight + networks	Aeromed data repository	
	WP4 - IT					Software	
	WP5 - Personal data					Data protection/ public safety	
	COM						



Part-MED Opinion

- Published on 15 August 2016

- Includes :
 - RMT.0287 Update of Part-MED

 - RMT.0700 Implementation of Germanwings Taskforce Recommendations

- Positive vote in May 2017 and February 2018

- Stopped during the Scrutiny procedure by the European Council

- Currently is put in the new format by the EC and will be presented for vote by the Member States



Part-MED: General

- Additional definitions to clarify medical terminology
- Aircrew obligations:
 - Requirements in case of suspension or revocation of the medical certificate
 - Enhanced requirements on decrease in medical fitness
- Simplified privileges of medical certificates holders
- Enhanced training, certification and oversight of AMEs
 - Practical training in Aeromedical Center
 - Competency based renewal/revalidation requirements for AME certificate
- Obligations for AME:
 - AMEs mandated to report fraud attempts
 - Inform applicants of their obligations in case of decrease of medical fitness



Part-MED: Medical Requirements

- New Mental Health requirements
 - Comprehensive mental health assessment for **initial** class 1 pilots
 - Psychiatric evaluation for applicants with a medical history of psychiatric conditions
 - Drugs and alcohol screening for **initial** class 1 pilots.

- Simplified requirements in case of pregnancy to allow aircrew to exercise privileges of their licenses until 26th week of pregnancy if no risk is foreseen for flight safety and for mother or foetus



Part-MED: Medical Requirements

- Setting the scene to align the assessment of medical conditions with new developments in the field of medicine:
 - Differential risk based assessment of aortic aneurism
 - Acceptance of Direct Oral Anticoagulation(DOAC)
 - Colour Assessment and Diagnosis (CAD) Test

- Simplified visual requirements

- New ORL limitation to allow class 2 pilots with certain medical conditions to fly without passengers or with a safety pilot



Part-MED: Achievements

- Safety is enhanced by improving fitness assessment and competency based training for AMEs
- Competency based criteria for renewal/ revalidation of AME Certificates provide flexibility for competent authorities to include previous performance of AMEs in the assessment
- Enhanced flexibility for class 2 medical certificate holders to support general aviation while maintaining the level of safety required
- Correcting editorial mistakes and ensuring consistency of wording for ease of implementation by the Member States



AMC/GM to Part-MED

- Draft AMC/ GM to undergo final revision after adoption of Part-MED

- Since consultation 3 topics raised concerns:
 - DOAC therapy for valve replacement

 - ORL Limitation

 - Crediting of aviation medical training of flight surgeons




AMC/GM to Part-MED -DOAC therapy for valve replacement

- Comments received from ESAM (Dr Rene Maire) showing that mechanical valve replacement does not have an indication for DOAC therapy
- New novel oral anticoagulants (e.g. Dabigatran, Rivaroxaban, Apixaban, Edoxaban, etc) are NOT licensed and are clearly CONTRA-INDICATED for use in patients with mechanical prosthetic heart valves.
 - Wales NHS - Anticoagulation in patients with heart valve replacements -Guideline for primary and secondary care.
- Pradaxa (dabigatran etexilate mesylate) should not be used in patients with mechanical prosthetic heart valves
 - FDA Drug Safety Communication
- Dabigatran versus Warfarin in Patients with Mechanical Heart Valves –
 - N Engl J Med 2013; 369:1206-1214 [September 26, 2013](#) DOI: 10.1056/NEJMoa1300615
- 1. Anticoagulant therapy with oral direct thrombin inhibitors or anti-Xa agents should not be used in patients with mechanical valve prostheses (277–279). (Level of Evidence: B) CLASS III: Harm
 - 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease



AMC/GM to Part-MED – ORL Limitation

- ORL Valid only with a safety pilot if passengers are carried and in aircraft with dual controls
 - This limitation applies to holders of a class 2 or LAPL medical certificate with a medical condition that may lead to an increased level of risk to flight safety when exercising the privileges of the licence. The safety pilot, if carried, should be made aware of the type(s) of possible incapacity that the pilot whose medical certificate has been issued with this limitation may suffer and should be prepared to take over the aircraft controls during flight. Refer to MED.B.001(d)(4).
- Flying with safety pilot and flying without passengers doesn't have the same level of safety, approx. 10% of accidents in GA resulted in third party fatalities or damage.
- ORL leaves the decision with the pilot rather than the AME
- Pilot  AME
- Proposal: keep ORL and add OSL as an option



AMC/GM to Part-MED – ORL Limitation

- AMC2 MED.B.010 (d)(1) Applicants with an aneurysm of the thoracic or supra-renal abdominal aorta of less than 5 cm in diameter may be assessed as fit with an ORL ~~OSL~~, subject to satisfactory cardiological evaluation. ~~and~~ ~~Regular~~ follow-up should be carried out.
- Proposal: keep ORL and add OSL as an option
- AMC2 MED.B.010 (d)(1) Applicants with an aneurysm of the thoracic or supra-renal abdominal aorta of less than 5 cm in diameter may be assessed as fit with an ORL or OSL, subject to satisfactory cardiological evaluation. Regular follow-up should be carried out.



AMC/GM to Part-MED – Flight surgeons

- Proposals to add military experience as relevant experience for AMEs as AMC to MED.D.015 - Extension of privileges and MED.D.030 – Validity of AME Certificates, as well as for the head of AeMC.



Referral

- In case a referral to or consultation with the licensing authority is in order, please follow the procedure established by the licensing authority of the applicant.
- Contact the medical assessor of the licensing authority of the applicant
- Get the necessary information regarding the referral or consultation procedure, as applicable
- Provide all the medical details of the case in a manner that will respect medical confidentiality principles
- Advise the applicant regarding the decision of fitness following the consultation with their licensing authority or the procedure to be followed in case of referral, as applicable.



COMPETENCY BASED TRAINING

- In order to be able to perform a reliable aero-medical assessment and to inspire your applicants with trust **MAINTAIN** your medical and aero-medical knowledge updated by identifying the weak points and attending at least the following activities:
 - Training sessions provided or supervised by your competent authority
 - International aero-medical conferences
 - AME peer group meetings and presenting your difficult cases as training for you and your peers

AME peer groups:

- A forum for professional discussion and collegial support
- Social interaction to enhance professional competency and build a stronger relationship between the AMEs/AeMCs in a region



Rulemaking activity

- Updated Part-MED expected to be adopted early 2019
- RMT.0287(b) – Update of the medical relevant parts of Part-ARA and Part-ORA – NPA published 21.12.2017; 400+ comments received
- RMT. 0424 – Regular update of Part-MED –ToR published on 09 Oct. 2017
- RMT.0707 - Medical Regulation — Combine Part-MED and Part ATCO MED – ToR scheduled for 2018
 - To include RPAS operators in class 3 provisions
 - To include Flight test engineers in class 2 provisions
 - Possibly to amend pilot age restrictions
- EC and EASA agreed to make a stop for all new EASA opinions until the EC has cleared the backlog of existing opinions.



Rulemaking activity

- Safety promotion
- Implementation support
- Scientific studies – Pilot age limits – kick-off meeting
14th Nov 2017
- Future projects under consideration
 - Colour vision
 - HIV
 - Risk assessment tool



EASA
European Aviation Safety Agency

Thank you for your attention!



medical@easa.europa.eu

Your safety is our mission.

An agency of the European Union 