EASA activities

update

AME refresher

Zagreb, Croatia

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Your safety is our mission.

An Agency of the European Union

Presentation Overview

- Rulemaking tasks
- Research activities
- EAMR

Rulemaking tasks

RMT.0287- Regular update of Part-MED

- Objectives:
  - To solve the inconsistency issues
  - To close the loopholes in the rules identified through the implementation experience
  - To keep the requirements up to date with the new developments in the field of medicine
  - To ensure it can be implemented in practice.

EASA

RMT.0287 was split in 2 subtasks

- Subtask 1: already finished, aimed to update the medical requirements included in Part-MED.
- Subtask 2: aims to update of the Subparts ARA.AeMC and ARA.MED of Part-ARA, and Subpart ORA.AeMC of Part-ORA , as well as of the related AMC and GM – **NPA 2017-022** consulted in Q1 2018

  - Includes the **Subtask 2b**, to explore the opportunity for raising the pilot age limit for single-pilot CAT operations in a gradual approach, starting with the HEMS.

Why is Subtask 2b necessary?

- **Flight crew engaged in single pilot commercial air transport operations can´t exercise the privileges of their licence beyond the age of 60** in accordance with the provisions of FCL.065(a) of the Aircrew Regulation.

- **The increasing retirement age** in EU (65 years in most of the EU countries) and the **longer life expectancy** has triggered several requests for exemptions mainly in emergency medical services.

- Since 2012 EASA have given positive recommendations to **7 exemption** notifications. These Exemptions, pertinent to the scope of this RMT, are **in accordance with Article 71** 'Flexibility provisions' of Regulation (EU) 2018/1139.

Why is Subtask 2b necessary?

- This situation led EASA to launch a research study in 2017 on the appropriateness of the existing pilot age limitations for commercial pilots.
- The results recommended extending the age limit for commercial air transport (CAT) pilots flying single pilot operations from 60 years to the pilot's 65th birthday, subject to mitigating measures.
- https://www.easa.europa.eu/en/document-library/research-reports/easarepresea20171

RMT.0287 (2)(b) ToR & GC

- ToR & CG published - 31/05/2021
  - to consider the increase of the age limit for pilots involved in single pilot HEMS operations from 60 to 65 and define the appropriate mitigating measures to ensure safety is not adversely affected.
- GC – 11 members representing MSs and industry:
  - FR, SI, FI, CH, ES, DE
  - EHA, EHAC, ECA, ESAM
  - EASA

Members:	
BECKER, Stefan – RMG Chair	EHA
GERMA, Rene	DGAC FR
KAMP, Raimund	MoT, DE
KOTNIK KERBEV, Mateja	CAA SI
PALLONEN, Janne	TRAFICOM
PECO ARREGUI, Carmen	EASA/SNE AESA
REMIE, Daan	EHAC
ROGNMO-HODGE, Andrew	ECA
SIMONS, Ries	ESAM
SZE, Leon	FOCA
PANAIT, Cristian Ionut – Group Secretary	EASA

RMT.0287 (2)(b) – consultation

- Once the draft regulatory text is available there is the intention to share it with MEG for a short peer review before the Focused consultation workshop.
- Focused consultation 05 May 2022 via virtual workshop including the MSs and industry.
  - Draft regulatory material shared with the participants in advance of the workshop
  - 76 participants
  - Participants asked that mitigating measures applicable also to other categories of pilots should be further discussed and agreed with the MEG
  - 2 weeks period after the Workshop (until 20 May) for written comments
  - 100+ comments received

RMT.0287 (2)(b) – mitigating measures

- Medical examination by the AeMCs or experienced AMEs
- Extended cardiovascular assessment at 60 and based on assessment of CV risk factors thereafter and to include at least:
  - resting ECG
  - exercise ECG
  - serum lipids
  - echocardiography
  - arterial doppler ultrasound including thoracic and abdominal aorta as well as carotid and femoral arteries
- Cardiovascular risk assessment starting after 40 years old
- Sleep apnoea screening
- Comprehensive examination of the ENT and visual system, including colour vision

RMT.0287 (2)(b) – mitigating measures(II)

- Operational mitigating measures
  - Fatigue risk management
  - Cognitive assessment during OPC
- Reporting of health data for pilots above the age of 60

RMT timeline remains the same for HEMS

- Opinion to be merged with the resulting text of NPA 2017-22 regarding updated to ARA.MED & ORA.AeMC.
- Opinion scheduled for Q1 2023

Other medical related tasks

- Update of FAK and EMK – **ED Decision 2021/005/R**
- RMT.0230 - Introduction of a regulatory framework for the operation of drones – discussion on medical requirements ‘Specific’ category.

Remote pilots: medical fitness requirements

Open	Specific	Certified
No requirements for **medical fitness** or **Fatigue and Stress management**	At the discretion of the NAA, depending on CONOPS and operational risk involved: Partial or full requirements for medical fitness and/or Fatigue and Stress management (EASA to provide recommendations in GM) Further discussions ongoing. MED recently involved in this task.	**OPS Type 1 (&2)** – Medical fitness conform ICAO Annex 1: **Class 3** Medical (ATCO medical fitness in CR 2015/340) or **Class 1** Medical (FCL medical fitness in CR 1178/2011) Adapted version of: ATCO **Fatigue and Stress management** provisions in CR 2017/373. No ICAO SARPS

Research

Research - ongoing

- EASA is a key part of the European Union's strategy to establish and maintain a high uniform level of safety in civil aviation at European level.
- A priority list of research topics in the fields of safety, security, environment and **health** has been proposed, which will serve to update the EASA research programme.
- Participation in this updating procedure is by means of a **tendering procedure** which is initiating.
- Financed under European research funds delegated to EASA as the researched actions to be listed in the EPAS

Research - ongoing

- Mental health
- Pilot and ACTOs aeromedical fitness research
  - Cardiovascular
  - Insulin treated diabetes mellitus
  - HIV – *no offer has been received*

Research - ongoing

- To allow the update of the requirements and AMC/GM according to the current scientific evidence in **mental health** in order to perform a better medical evaluation of pilots and ATCOs
- To have the scientific evidence to include new developments in both the cardiovascular and diabetes mellitus in the current regulatory framework

Mental health research - MESAFE

- Mind is the most difficult system to assess for a pilot or an ATCO to discharge their tasks safely.
- In most mental health pathologies, including addictions, constant symptoms are denial and dissimulation making them very difficult to identify.
- Currently there are no specific validated mental health assessment methods for aviation use, incorporating the operational needs, to address the issues identified.
- Research is needed to further detail the specific needs and to develop and validate assessment methods or to assess the applicability of existing methods for the use in aviation.

MESAFE
MEntal health for aviation SAFEty

Mental health research - MESAFE

- Mental health assessment may have more than one goal
  - some are intended to evaluate the overall fitness to perform,
  - others are intended to evaluate the synergy between the pilot/ATCO profile and a specific type of operations,
  - others are intended to identify certain sequelae after special circumstances (involvement in an accident/serious incident, loss of a family member, etc) which may affect their performance.

ATCO and Pilot Fitness research

- New development in medicine may have an impact on the assessment of fitness of pilots and ATCOs. The study looks at 2 areas that have been requested by our stakeholders, namely diabetes mellitus and cardiovascular conditions
- Call for tenders published on 20th December 2021
- Deadline to submit the offers: 30th March 2022
- Duration: 36 months

ATCO and Pilot Fitness research (II)

- Medical science is evolving continuously. Medical requirements for pilots and ATCOs are expected to evolve with the science and become evidence based.
- For certain conditions the side effects of the treatment may be more dangerous for safety relevant positions than the condition itself.
- The study looks at 3 areas that have been requested by our stakeholders, namely:
  - Diabetes mellitus – with focus on insulin treated diabetes
  - Cardiovascular medical conditions – the diagnostic and treatment guidelines of the European Society of Cardiology have been recently updated which will have an impact on treatments and diagnostic measures available and acceptable for use in aviation.

ATCO and Pilot Fitness research(III)

- The scope of the lots includes:
  - Assessment of the existing requirements relevant for the topics
  - Identifying new medical diagnostic tools and treatments suitable for use in the aviation environment
  - Provide recommendation on implementation of these diagnostic tools and treatment measures
  - Provide training materials for AMEs and aviation personnel

ATCO and Pilot Fitness research(IV)

- The contractor is required to produce the following:
  - a synopsis of the state-of-the-art in each of the domains that is perceived by the tenderer as relevant to the conduct of the current study, i.e., recent (2015 to date) scientific literature, analytical methods, as well as methods to assess and compare an outline of the research approach that is proposed to tackle each individual task together with a succinct rationale justifying its adoption;
  - a list of perceived risks and assumptions that may undermine the fulfilment of all or some of the objectives put forward by this tender;
  - deliverables that describe in detail the results of each task;
  - any other additional element considered relevant that may bear on the duly completion of the work, e.g., access to relevant information, required input from third parties.
- Potential challenges:
  - Continuous evolution of medical field
  - Relatively large scope for each of the lots
  - Extensive needs including recommendations for rulemaking and training material

Research – ideas for the future

- Colour vision needs for pilots and ATCOs in new working environments
- VR training for pilots – assessing the impact on fitness
- Medication
- Risk assessment matrix
- Other suggestions???

EAMR

Background

- Following GW accident, EASA was instructed to develop a database of medical certificates for pilots in order to prevent medical tourism and fraud attempts
- Initially the developer could not provide a solution stable enough to be accepted
- EASA decided to search for alternatives solution in order to provide a stable an usable product to ensure compliance with the GW Taskforce recommendations and with the Part ARA requirements.
- Currently the discussions with Microsoft to find other solutions, resulted in a new project to renovate the CRM and to create a new portal.
- A design workshop took place 19-20 Aug 2019 with MS participation

Background

- Following the adoption of Regulation 2018/1139 – a repository for information has to be developed in accordance with art. 74
- The repository should include medical certificates for pilots and ATCOs
- The national competent authorities, aeromedical examiners and aeromedical centres shall also exchange through the repository information concerning medical fitness of pilots.

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REGULATIONS

* **Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91** [1] — 1

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

Top

EAMR development

- Currently the system is stable following rework from Microsoft on the CRM. The system is already ready for the 2021 upgrades of the CRM and portal.
- One off import of the existing NAA staff, class 1 AMEs and class 1 applicants is foreseen to further reduce the workload on the NAAs where required data can be provided – email address mandatory for AMEs and applicants
- Integration with national systems to be investigated for the next step, especially in the context of extending the scope to art. 74 repository

Implementation calendar

- **4 Train the trainers sessions for NAA staff performed for 1st , 2nd , 7th and 8th of June**
- **Go Live 30th June**
- **Transition period until 31st December 2021** (initially to 1st Oct, re-assessment of mandatory use in September 2021 led to postponement of the mandatory phase to 1st January 2022)
- **Dedicated meeting on 15th September 2021**
- **Training materials are available on EASA website**
- **Backlog of issues raised but starting to be solved**
- Deduplication engine was temporary down, but issue was solved about 3 weeks ago.

NAA platform

- **Main issues reported so far related to access rights:**
  - For NAA staff the links to be used are:
    - **Real** (production) environment: https://euaviation.crm4.dynamics.com/main.aspx
    - **Training** environment: https://euaviationtest.crm4.dynamics.com/
  - **The username should be firstname.lastname@eamr.eu**
    - For example cristian.panait@eamr.eu

- **Problem with the licensing authority following the import of applicants**

Portal for AMEs and applicants

- **Main issues reported so far related to access rights:**
  - For the portal the links to be used are:
    - **Real** (production) environment: https://euaviation.powerappsportals.com/
    - **Training** environment: https://euaviationtest.microsoftcrmportals.com/

- Many AMEs had problems working in the portal after logging in due to problems with validity – issue solved

- Send issues via email to EAMR-Support@easa.europa.eu

EAMR Implementation plan

- 30 January 2020 – UAT with the NAAs
- 05, 06 & 09 March 2020 – Train the trainers
  - COVID-19 pandemic did not allowed all registered participants to attend the training
- 02, 04, 07, 08 & 10 June 2021 – 5 sessions - Train the trainers
- June-September 2021 –training at national level for AMEs and NAA staff

- **01 January 2022 – mandatory use by all AMEs&AeMCs for all class 1 pilots**

Current status

- Starting **01 October 2021 – GO LIVE**
- **Transition period until 31st December 2021 (**re-assessment of mandatory use in September 2021**)**
- As of **01 January 2022 – mandatory use** of the EAMR by the NAAs and AMEs
- Training materials available on EASA website

EAMR Implementation

- Most MSs have started implementation
- Several states minimal using – need to ramp-up the use of EAMR
- 2 MSs did not attend the training nor start the implementation
  - During STD we monitor the implementation – two MSs already received a finding related to ARA.MED.160
- One MSs submitted an art 71.1 Exemption notification regarding the upload of data while attempting to link the national electronic system with the EAMR

EAMR Implementation

- Several tickets still open due to be closed by the end of June.
  - Most tickets related to access rights – reset password
  - Few tickets on functionalities of the portal for specific AMEs
  - Deduplication system generated an excessive number of potential duplicates – our external provider is working to reset it. MAs were informed not to waste resources on the assessment of potential duplicates for the time being
- AMEs should search for the applicants before creating new applicants.

Conclusions

- NAAs should promote the proper use of EAMR by the AMEs
- NAAs should ramp-up the use of EAMR
- NAAs& AMEs should report the issues to

  EAMR-Support@easa.europa.eu

Standardisation & harmonisation

Principles

- Main principles are:
  - Freedom of movement
  - Mutual recognition
  - Equal level of safety
  - Equal treatment of aircrew and ATCOs throughout EU

Standardisation inspection

- Regulation (EU) No 628/2013
- EASA visits the National Competent Authorities(NCA) to assess
  - Implementation of Part-MED & Part ACTO.MED
  - Implementation of authority requirements including,
    - Certification of AMEs, AeMCs, GMPs
    - Oversight over their AMEs, AeMCs, GMPs
    - Medical certification of aircrew and ATCOs
- As part of the visit to the NCA, EASA visits undertakings to sample how the NCA is completing its tasks

Visits to undertakings and UNCs

- Undertakings are visited as samples to evaluate the NCA's oversight.
- No findings, can be raised by EASA against undertakings,
- When **undertakings' non-compliances (UNC)** are identified they are usually linked with/evidence of a finding for the NCA
- but all the **undertakings' non-compliances (UNC)** detected shall be recorded and monitored by EASA.

Inspection programme

	MON	TUE	WED	THU	FRI
	DD	DD	DD	DD	DD
AM	-	NAA	AeMC/AME	AME	NAA?
PM	NAA?	AeMC	AME	NAA	-

Be aware!

MED.A.025 Obligations of the AeMC, AME, GMP and OHMP

- (a)When conducting aero-medical examinations and aero-medical assessments as required in this Annex (Part-MED), the AeMC, AME, GMP and OHMP shall:
  - (1) ensure that communication with the applicant can be established without language barriers;
  - (2) make the applicant aware of the consequences of providing incomplete, inaccurate or false statements on their medical history;
  - (3) notify the licensing authority, or, in the case of cabin crew attestation holders, notify the competent authority, if the applicant provides incomplete, inaccurate or false statements on their medical history;
  - (4) notify the licensing authority if an applicant withdraws the application for a medical certificate at any stage of the process.

Be aware!

MED.A.025 Obligations of the AeMC, AME, GMP and OHMP

- (b) After completion of the aero-medical examinations and assessments, the AeMC, AME, GMP and OHMP shall:
  - (4) in the case of applicants for a medical certificate, submit without delay to the medical assessor of the licensing authority a signed, or electronically authenticated, report containing the detailed results of the aero-medical examinations and assessments as required for the class of medical certificate and a copy of the application form, the examination form, and the medical certificate;
- (f) AeMCs and AMEs shall enter or update the data included in the European Aero-Medical Repository in accordance with point (c) of point ARA.MED.160.

Be aware!

MED.B.055 Mental Health

- (a) Comprehensive mental health assessment shall form part of the initial class 1 aero-medical examination.
- (b) Drugs and alcohol screening shall form part of the initial class 1 aero-medical examination.
- (e) Applicants with a documented medical history of a single or repeated acts of deliberate self-harm or suicide attempt shall be assessed as unfit. However, they may be assessed as fit after satisfactory psychiatric evaluation.
- (g) Applicants with a documented medical history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder shall be assessed as unfit.

Be aware!

AMC 1 MED.B.055 Mental Health

- (d) Psychoactive substance testing
  - (1) Drug tests should screen for opioids, cannabinoids, amphetamines, cocaine, hallucinogens and sedative hypnotics. Following a risk assessment performed by the competent authority on the target population, screening tests may include additional drugs.
  - (2) For renewal/revalidation, random psychoactive substance screening test may be performed based on the risk assessment by the competent authority on the target population. If random psychoactive substance screening test is considered, it should be performed and reported in accordance with the procedures developed by the competent authority.
  - (3) In the case of a positive psychoactive substance screening result, confirmation should be required in accordance with national standards and procedures for psychoactive substance testing.

Be aware!

MED.D.015 Requirements for the extension of privileges

- (d) they have successfully completed **practical training of a duration of at least 2 days**, either at an AeMC or under the supervision of the competent authority.

Be aware!

MED.D.030 Validity of AME certificate

- (6) has demonstrated that he or she maintains **his or her aero-medical competency in accordance with the procedure** established by the competent authority.

Be aware!

ARA.MED.315 Review of examination reports

- The licensing authority shall have **a process** in place to:
  - (a) review examination and assessment reports received from the AeMCs, AMEs and GMPs and inform them of any inconsistencies, mistakes or errors made in the assessment process; and
  - (b) assist AMEs and AeMCs on their request regarding their decision on aero-medical fitness in contentious cases.

Be aware!

MED.D.005 Application

- (b) Applicants for an AME certificate shall provide the competent authority with:

  (3) **a written declaration** that, once the AME certificate has been issued, the AME will issue medical certificates on the basis of the requirements of this Regulation.

Be aware!

AMC1 MED.D.030 Validity of AME certificates

REFRESHER TRAINING

(a) It is the responsibility of the AME to continuously maintain and improve their competencies.

(b) During the period of validity of the AME certificate, an AME should attend a minimum of **20 hours of refresher training.**

(c) **An AME exercising class 1 privileges should attend at least 10 hours of refresher training per year.**

(d) A proportionate number of refresher training hours should be provided by, or conducted under the direct supervision of, the competent authority or the medical assessor.

(e) The curricula of refresher training hours referred to in (c) should be **decided by the competent authority following a risk-based assessment.**

….

(g) In case of renewal of an AME certificate, the practical training should include at least 10 aero-medical assessments, **in accordance with the type of the requested AME certificate**.

Be aware!

GM1 MED.D.030 Validity of AME certificates

REFRESHER TRAINING

(c) **An AME exercising class 1 revalidation/renewal privileges should attend international aviation medicine scientific meetings or congresses at regular intervals.**

(d) **Aero-medical examinations of military pilots** may be considered as equivalent in accordance with MED.D.030(a)(3), subject to approval by the medical assessor of the competent authority.

Be aware!

GM1 MED.D.030 Validity of AME certificates

REFRESHER TRAINING

(a) The curricula for the refresher training hours that should be provided by, or conducted under the **direct supervision of, the competent authority or the medical assessor** may include but are not limited to subjects such as:

(1) Psychiatry;

(2) Psychology

(3) Communication and interview techniques

(b) Scientific meetings, congresses or flight deck experience that may be credited by the competent authority:

International Academy of Aviation and Space Medicine Annual Congresses (ICASM)	**10 hours credit**
European Conference of Aerospace Medicine (ECAM)	**10 hours credit**
Aerospace Medical Association Annual Scientific Meetings (AsMA)	**10 hours credit**
Other scientific meetings (A minimum of 6 hours to be under the direct supervision of the medical assessor of the competent authority)	**10 hours credit**

Follow-up and closure

- Corrective action plan:
  - Includes one or more actions to remediate the non-compliance
  - In case of UNCs, it includes also measures to address the non-compliances identified in the undertakings
  - Agreement with EASA on the action plan and deadlines
- Deadlines:
  - provide proposed corrections action plan at the earliest convenience;
  - provide agreed correction until Due date;
- Implementation:
  - Provide evidence of implementation

EASA
European Union Aviation Safety Agency

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