

Annex III to ED Decision 2025/002/R

'AMC and GM to Part-MED — Issue 2, Amendment 1'

The text of the amendment is arranged to show deleted, new and unchanged text as follows:

- deleted text is ~~struck through~~;
- new or amended text is highlighted in blue;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

Note to the reader

In amended, and in particular in existing (that is, unchanged) text, 'Agency' is used interchangeably with 'EASA'. The interchangeable use of these two terms is more apparent in the consolidated versions. Therefore, please note that both terms refer to the 'European Union Aviation Safety Agency (EASA)'.

Annex I to Decision 2019/002/R of the Executive Director of the Agency of 28 January 2019 is amended as follows:

SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

SECTION 2 — MEDICAL REQUIREMENTS FOR CLASS 1 AND CLASS 2 MEDICAL CERTIFICATES

In Subpart B 'REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES', Section 2 is amended as follows:

AMC1 MED.B.010 Cardiovascular system

(a) Examination

Exercise electrocardiography

An exercise ECG when required as part of a cardiovascular assessment should be symptom limited and completed to a minimum of Bruce Stage IV or equivalent.

(b) General

(1) Cardiovascular risk factor assessment

- (i) Serum lipid estimation is case finding and significant abnormalities should be reviewed, investigated and supervised by the AeMC or AME in consultation with the medical assessor of the licensing authority.
- (ii) Applicants with an accumulation of **two or more** risk factors (~~smoking, family history, lipid abnormalities, hypertension, etc.~~) should undergo a cardiovascular evaluation by the AeMC or AME, if necessary in consultation with the medical assessor of the licensing authority.
- (iii) **Cardiovascular risk factor assessment should be performed using risk calculators relevant for the target population and taking into consideration the latest guidelines on cardiovascular disease prevention.**
- (iv) **Cardiovascular risk factor assessment should take place at least once every 5 years for applicants 40 to 49 years old, once every 3 years for applicants 50 to 59 years old and once every 2 years thereafter. A more frequent assessment of the cardiovascular risk factors may be considered when risk factors have been identified.**

(2) Cardiovascular assessment

- (i) Reporting of resting and exercise electrocardiograms should be by the AME or an accredited specialist.
- (ii) The extended cardiovascular assessment should be undertaken at an AeMC or may be delegated to a cardiologist.

- (iii) For applicants involved in single-pilot HEMS operations who have reached the age of 60, the extended cardiovascular assessment should include at least the following elements:
- (A) resting ECG;
 - (B) exercise ECG;
 - (C) serum lipids;
 - (D) glycosylated haemoglobin test (HbA1c);
 - (E) echocardiography;
 - (F) arterial doppler ultrasound carotid arteries, and at clinical indication thoracic or abdominal aorta could be considered.

[...]

Rationale

RMT.0287

The study on pilot age limits considered that the extension of pilot age limit for certain single-pilot operations is possible with mitigating measures in place. Based on the recommendations of the study and the discussions in the Medical Experts' Group (MEG), this AMC was updated to clarify the content of the extended cardiovascular assessment as well as the type of risk calculators and the intervals for the regular cardiovascular risk factor assessment.

AMC2 MED.B.010 Cardiovascular system

[...]

(b) General

(1) Cardiovascular risk factor assessment

Cardiovascular risk factor assessment should take place at least once every 5 years for applicants 40 to 59 years old, and once every 2 years thereafter. A more frequent assessment of the cardiovascular risk factors may be considered when risk factors have been identified.

Applicants with an accumulation of **two or more** risk factors (~~smoking, family history, lipid abnormalities, hypertension, etc.~~) should undergo a cardiovascular evaluation by the AeMC or AME.

(2) Cardiovascular assessment

Reporting of resting and exercise electrocardiograms should be by the AME or an accredited specialist.

[...]

(l) Rhythm and conduction disturbances

[...]

(6) Complete right bundle branch block

Applicants with complete right bundle branch block ~~may be assessed as fit with appropriate limitations, such as an ORL, and subject to satisfactory cardiological evaluation~~ should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

[...]

Rationale	<i>RMT.0287</i>
<p>Recent guidelines of the European Society of Cardiology highlighted the value of monitoring and early management of cardiovascular risk factors in preventing cardiovascular events. This can be translated into reducing the risk of incapacitation due to cardiovascular reasons. Consequently, the rulemaking group proposed to clarify the intervals for the regular cardiovascular risk factor assessment.</p> <p>Additionally, the rulemaking group proposed to correct inconsistencies related to the means of compliance regarding the class 2 applicants with complete right bundle branch block.</p>	

GM1 MED.B.010(b) Cardiovascular system

(a) Cardiovascular risk factor assessment

A risk calculator is constructed as an equation with regression coefficients for each included risk factor, based on a statistical analysis of data from a population of a certain region to provide a crude risk estimate. A risk calculator to be used for screening of CAT pilots should be relevant for the ethnicity of the pilots being screened and should predict the 5–10-year risk for non-fatal events such as acute coronary syndromes or stroke, as well as fatal cardiac events, as both may lead to total in-flight incapacitation.

It is recommended to use a risk estimation tool that is based on populations similar to your most common target population. No risk calculator is perfect, and an assessment of advantages and disadvantages should be made when deciding on which tools should be used. For example, the most common tools that are based on European population are: SCORE 2, PROCAM, AGLA and QRISK 3.

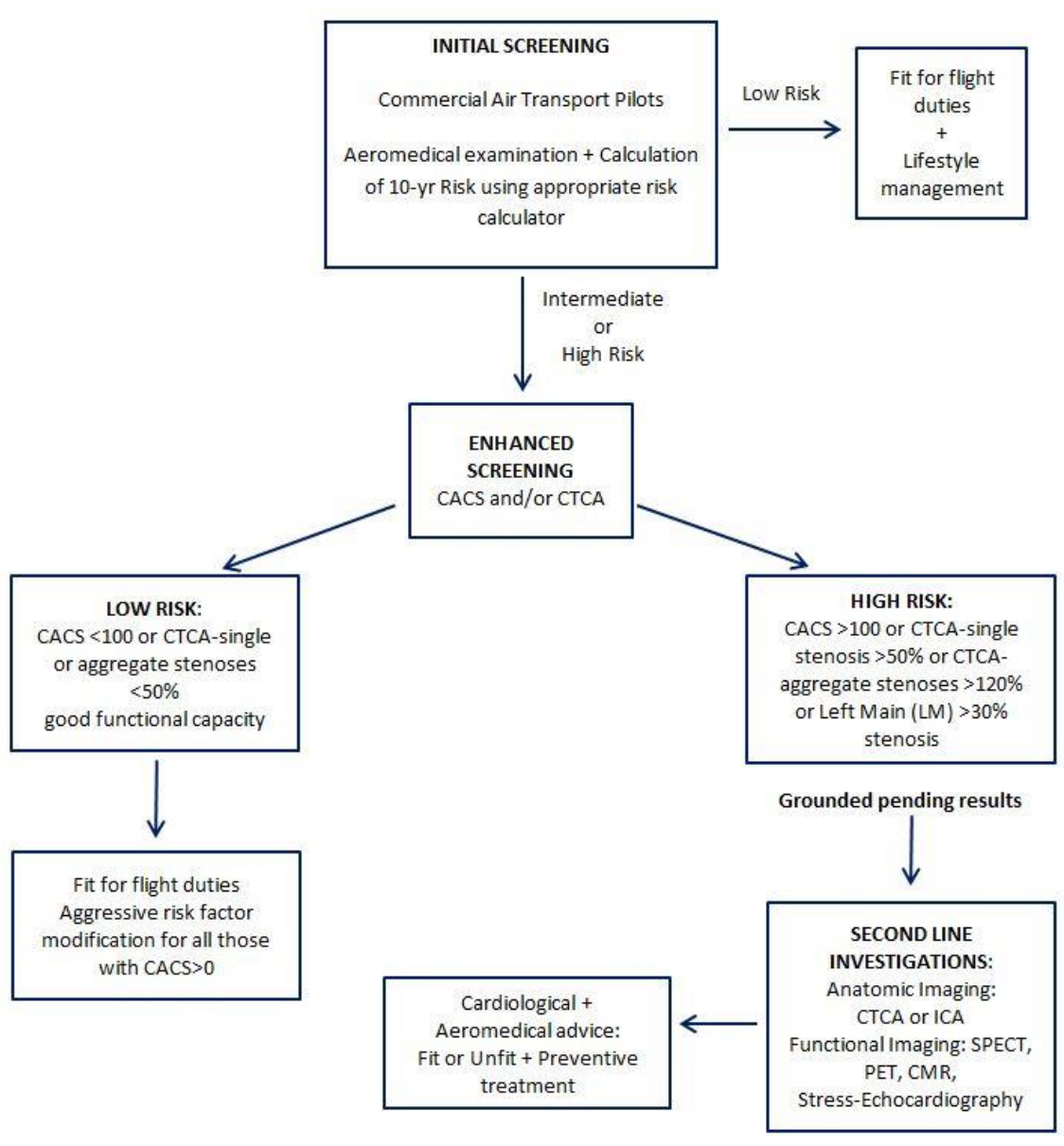
In the risk assessment AMEs should give proper consideration to the latest published guidance of the European Society of Cardiology. At the time of the drafting, the most recent guidelines are '[2021 ESC Guidelines on cardiovascular disease prevention in clinical practice](#)'.

(b) Cardiovascular assessment

It is recommended that for applicants involved in single-pilot HEMS operations who have reached the age of 60, the cardiovascular assessment considers the risk level when deciding on enhanced screening investigations.

In this regard the following flow chart algorithm adapted by Simons et al. (2019) from Gray et al.(2019) is aimed at supporting AMEs and medical assessors. The classification of low, intermediate or high risk is given by the cardiovascular score being used. The enhanced screening investigations are in the realm of the consultant cardiologist.

Abbreviations used in the flowchart: CACS=Coronary Artery Calcium Score; CTCA=Computed Tomography Coronary Angiography; SPECT=Single-Positron Emission Tomography; PET=Positron Emission Tomography; CMR=Cardiac Magnetic Resonance; ICA= Invasive Coronary Angiography. [Simons et al. (2019)]



Rationale

RMT.0287

Considering the guidance from the European Society of Cardiology and the recommendations of the EASA study on pilot age limits, the rulemaking group proposed to add this GM to provide best practice guidelines on cardiovascular risk factors' assessment as well as the cardiovascular assessment of pilots who have reached the age of 60 years in single-pilot HEMS operations.

AMC1 MED.B.015 Respiratory system

(a) Examination

(1) Spirometry

A spirometric examination is required by points MED.B.015 (b) and (c) for ~~initial examination and on clinical indication~~ applicants for a class 1 medical certificate in specific situations. Applicants with an FEV1/FVC ratio of less than 70 % should be evaluated by a specialist in respiratory disease.

(2) Chest radiography

Posterior/anterior chest radiography may be required at initial, revalidation or renewal examinations if clinically or epidemiologically indicated

[...]

(h) Sleep apnoea syndrome/sleep disorder

Applicants with unsatisfactorily treated sleep apnoea syndrome should be assessed as unfit.

Obstructive sleep apnoea (OSA) screening should include an anamnestic interview and assessment of OSA risk factors such as increased BMI, and a history of cardiovascular, cerebrovascular, metabolic and ENT pathology.

Rationale

RMT.0287

The rulemaking group and the discussions in the Medical Experts' Group (MEG) highlighted the importance of a proper anamnestic interview and OSA risk factors' assessment for the early detection of applicants suffering from or being at high risk of OSA, resulting in the pilots commencing treatment and risk factor management as early as possible to be able to reduce the risks related to OSA and keep flying safely. Consequently, this AMC was updated to provide clarifications on the content of the OSA screening.

GM1 MED.B.015 Respiratory system**SCREENING OF THE OBSTRUCTIVE SLEEP APNOEA (OSA) SYNDROME**

(a) AMEs may consider the following algorithm when screening their applicants regarding the OSA syndrome:

Assessment of OSA risk may be considered at every medical examination of pilots through scores that combine history questions with physical findings such as the STOP-BANG score.

(b) AME guidance:

Indicators to initiate OSA evaluation

— History interview including at least the following:

- Daytime sleepiness (i.e. Epworth Sleepiness Scale)?
- Snoring (what does spouse/partner say?)
- Psychosocial issues due to sleepiness, heavy snoring
- Observable apnoea episodes

- Contributing factors:
 - BMI >30
 - Previous bariatric history
- Neck circumference: ≥ 40 cm
- Diagnosed arterial hypertension
- Heart troubles
 - Arrhythmia
 - Congestive heart failure
 - CHD
- Previous TIA, stroke
- Diabetes Type 2
- ENT
 - Nasal obstruction
 - Orthodontic/Retrognathia
 - Oropharyngeal examination –e.g. modified Mallampati Score or Friedman tongue position

Methodology (if indicated):

- Nocturnal oximetry
- Respiratory polygraphy
- Polysomnography in certified sleep laboratories
- Eventually evaluation of vigilance:
 - Maintenance of Wakefulness Test (MWT)
 - Multiple Sleep Latency Test (MSLT)

Rationale

RMT.0287

The rulemaking group and the discussions in the Medical Experts' Group (MEG) highlighted the importance of a proper anamnestic interview and OSA risk factors' assessment for the early detection of applicants suffering from or being at high risk of OSA, resulting in the pilots commencing treatment and risk factor management as early as possible to be able to reduce the risks related to OSA and keep flying safely. Consequently, this GM was added to provide best practice recommendations on how to conduct the OSA screening and follow-up evaluation.

AMC1 MED.B.055 Mental health

[...]

(e) Assessment and referral decisions

[...]

(10) Cognitive disorders

(i) Applicants who exhibit signs of cognitive disorders should undergo a satisfactory neuropsychiatric evaluation to assess the severity of the cognitive impairment before a fit assessment may be considered. Applicants with mild cognitive impairment may be assessed as fit with an OML limitation and regular monitoring of the cognitive decline.

(ii) For applicants above the age of 60 performing single-pilot HEMS operations, AMEs should pay particular attention to early signs of cognitive decline. A comprehensive specialist evaluation should be considered where the medical assessors received information from the personnel performing regular training and checking of these applicants in accordance with ORO.FC.230 or AMEs performing the recurrent aero-medical examination documenting a potential cognitive decline of such pilots.

(1011) Assessment

The assessment should take into consideration ~~if~~ whether the indication for the treatment, side effects and addiction risks of such treatment and the characteristics of the psychiatric disorder are compatible with flight safety.

[...]

Rationale

RMT.0287

The rulemaking group and the discussions in the Medical Experts' Group (MEG) regarding the alleviation to pilot age limits for HEMS pilots highlighted the importance of including among the mitigating measures an assessment of the cognitive function in order to be able to detect early signs of cognitive decline. At the same time, during the discussions it became obvious that clarification is needed regarding the fitness of applicants involved in multi-pilot operations exhibiting signs of cognitive disorders.

Consequently, the rulemaking group proposed to add a new point to AMC1 MED.B.055 to tackle both issues.

AMC1 MED.B.070 Visual system

(a) Eye examination

(1) At each aero-medical examination, an assessment of the visual fitness should be undertaken and the eyes should be examined with regard to possible pathology.

(2) All abnormal and doubtful cases should be referred to an ophthalmologist. Conditions which indicate ophthalmological examination include but are not limited to a substantial

decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity and/or the occurrence of eye disease, eye injury, or eye surgery.

- (3) Where specialist ophthalmological examinations are required for any significant reason, this should be imposed as a limitation on the medical certificate.
- (4) The possible cumulative effect of more than one eye condition should be evaluated by an ophthalmologist.
- (5) In their examination AMEs should give proper consideration to the degenerative effects of ageing on the visual system.

(b) Comprehensive eye examination

A comprehensive eye examination by an eye specialist is required at the initial examination. All abnormal and doubtful cases should be referred to an ophthalmologist. The examination should include:

- (1) history;
- (2) visual acuities near, intermediate and distant vision (uncorrected and with best optical correction if needed). Where a degeneration of the visual acuity is observed, additional specialised examinations could be considered, subject to the suspected pathology;
- (3) examination of the external eye, anatomy, media (slit lamp) and funduscopy;
- (4) ocular motility;
- (5) binocular vision;
- (6) visual fields;
- (7) tonometry on clinical indication and for all cases where a comprehensive eye examination is required for applicants over the age of 45;
- (8) objective refraction: hyperopic initial applicants with a hyperopia of more than +2 dioptres and under the age of 25 should undergo objective refraction in cycloplegia;
- (9) assessment of mesopic contrast sensitivity; and
- (10) colour vision.

(c) Routine eye examination

A routine eye examination may be performed by an AME and should include:

- (1) history;
- (2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
- (3) examination of the external eye, anatomy, media and funduscopy; and
- (4) contrast sensitivity assessment test for applicants above the age of 60; and
- (5) further examination on clinical indication.

[...]

Rationale

RMT.0287

As a result of a safety recommendation received, EASA proposed for discussion in the rulemaking group and the MEG meeting the need to highlight in the AMC the degenerative effects of ageing on the visual system and in particular for the visual acuity and contrast sensitivity.

The rulemaking group accepted the EASA proposal and the AMC was updated accordingly.

AMC2 MED.B.070 Visual system

(a) Eye examination

- (1) At each aero-medical revalidation examination an assessment of the visual fitness of the applicant should be undertaken and the eyes should be examined with regard to possible pathology. Conditions which indicate further ophthalmological examination include but are not limited to a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity and/or the occurrence of eye disease, eye injury, or eye surgery.
- (2) At the initial assessment, the examination should include:
 - (i) history;
 - (ii) visual acuities near, intermediate and distant vision (uncorrected and with best optical correction if needed);
 - (iii) examination of the external eye, anatomy, media and funduscopy;
 - (iv) ocular motility;
 - (v) binocular vision;
 - (vi) visual fields;
 - (vii) colour vision;
 - (viii) further examination on clinical indication.
- (3) At the initial assessment the applicant should submit a copy of the recent spectacle prescription if visual correction is required to meet the visual requirements.
- (4) In their examination AMEs should give proper consideration to the degenerative effects of ageing on the visual system

(b) Routine eye examination

A routine eye examination should include:

- (1) history;
- (2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
- (3) examination of the external eye, anatomy, media and funduscopy;
- (4) contrast sensitivity assessment test for applicants above the age of 60; and

(5) further examination on clinical indication.

[...]

Rationale*RMT.0287*

As a result of a safety recommendation received, EASA proposed for discussion in the rulemaking group and the MEG meeting the need to highlight in the AMC the degenerative effects of ageing on the visual system and in particular for the visual acuity and contrast sensitivity.

The rulemaking group accepted the EASA proposal and the AMC was updated accordingly.