Draft amendments to Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Part-MED

RMT.0287(b) (MED.001)

Important note:

This file is published for information purposes only. No quality control has been performed yet. The draft AMC and GM contained in this file already contains some updates resulting from written consultation with the EASA Medical Expert Group in August 2023. Further changes may occur for further alignment of draft AMC and GM with the corresponding draft implementing rules in the course of the adoption process.



This AMC and GM to Part-XX Amendment/Issue X document (Annex to ED Decision 202X/XXX/R) shows deleted text, new or amended text as follows:

The amendment(s) is (are) arranged as follows to show deleted, new, and unchanged:

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

Where necessary, the rationale is provided in *italics*.

1.1. Draft acceptable means of compliance and guidance material (Draft EASA decision)

1.1.1. AMC/GM to Part ARA

Subpart MED SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION is amended as follows:

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

SECTION I — GENERAL

AMC1 ARA.MED.120 Medical assessors

EXPERIENCE AND KNOWLEDGE

Medical assessors should:

- (a) have considerable experience of aero-medical practice, having held AME privileges for at least
 5 years and having undertaken a minimum of 200 class 1 or class 3 medical examinations, or equivalent;
- (b) have specific training on the regulatory processes and aero-medical certification of referred cases; and
- (bc) maintain their medical professional competence in aviation medicine. The following should count towards maintaining medical professional competence:
 - (1) undertaking regular refresher training;
 - (2) participating in international aviation medicine conferences;
 - (3) undertaking research activities, including publication of results of the research.



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AMC2 ARA.MED.120 Medical assessors

TASKS

Medical assessors' tasks should include:

- (a) provide to approve and oversee lectures in basic, advanced and refresher training courses for aero-medical examiners (AMEs) and aero-medical centres (AeMCs).; Medical assessors may also deliver lectures during those training courses provided that a procedure is in place to avoid conflict of interest;
- (b) to carry-out supervision and audits of AeMCs, AMEs and AME training facilities; and
- (c) to perform the aero-medical assessment of applicants for, or holders of, medical certificates after in case of consultation, referral, to the licensing authority secondary review or when medical certificates have been issued by non-compliant AMEs ;-
- (d) to certify and oversee AeMCs and AMEs, including reviewing of medical files submitted by them to the competent authority;
- (e) to manage medical files including transfers of medical files in case of a change of state of licence issue;
- (f) to assist AMEs and AeMCs, on their request, regarding aero-medical fitness assessments in borderline and difficult cases or cases not regulated in Part-MED or Part-ATCO.MED, as applicable; and
- (g) to issue a medical certificate if a case is referred or if corrections to the information of a medical certificate are necessary.

AMC3 ARA.MED.120 Medical assessors

The medical assessor may delegate certain tasks to other staff designated by the competent authority or contract agents. The competent authority should ensure that such person has relevant training and experience for the delegated task and that the entire process is properly documented.

GM1 ARA.MED.120 Medical assessors

DELEGATION OF MEDICAL ASSESSOR'S TASKS

Properly qualified medical assessors are essential for maintaining flight safety and an efficient and functional aero-medical system. Medical assessors, like any inspector of the competent authority, should, by their qualifications and competencies, command the professional respect of the personnel and organisations they inspect, authorise, or oversee. These guidelines aim to establish possible solutions to optimise the use of qualified medical assessors as well as temporary solutions until properly qualified medical assessors are readily available. These guidelines should be interpreted and implemented only to the extent that they provide for sound and effective oversight in accordance with principles of the safety risk management.

For all of the medical assessor's tasks, the support staff may provide administrative support in regard to the paperwork and preparation work. Furthermore, some tasks may be partially delegated to other staff members of the competent authority. The medical assessor should select to whom the tasks are delegated based on their qualifications in order to ensure that the entire performance is in line with the applicable provision both in the field of aviation and in the medical field and is properly documented. The compliance



monitoring system of the competent authority should ensure that delegation of certain tasks has no negative impact on issues related to flight safety and data protection.

In order to maintain their medical proficiency the medical assessors may act as an AME subject to the proper procedure in place to avoid conflict of interest.

The following steps may be considered when required:

(a) Employment of a not fully qualified medical assessor.

When recruiting a fully qualified medical assessor is not possible the competent authority may employ a medical doctor to be trained and nominated as a medical assessor once the training is finalised. The performance of these doctors should be supervised by a qualified medical assessor from the pool of experts.

(b) Assign role to qualified inspectors as a team member (e.g. assessing the SMS system of an AeMC).

In this context, the qualified inspectors performing duties within the inspection/oversight team are expected to document their work and to report to the medical assessor as the accountable person for the process.

(c) Use an appropriately qualified medical assessors and AMEs from pool of experts.

The use of AMEs or MAs from a pool of experts should be limited to the sharing of experts to cover unplanned activity or temporary/transitional shortage of expertise rather than a consistent long term use.

The following types of expert pools may be considered:

- qualified AMEs
- medical assessors from the NAAs of other States or EASA
- medical assessors/AMEs from military aviation.

The following risks should be assessed and mitigated in case of using a pool of experts:

- assessment and oversight of expert's performance as well as enforcement in case of noncompliance.
- authorisation of the expert to: access medical practices, investigate, conduct interviews, and collect evidence.
- financial, contracting and administrative aspects; recurrent training on administrative procedures.
- ability of the nominated expert to write reports and findings.
- avoidance of conflict of interest;
- sustainability (i.e. to avoid to permanently rely on the pool of experts);
- commercial sensitivity of AMEs/AeMCs, cultural issues.
- data protection issues
- language barriers
- recognition between states, including the right to practice medicine in a different State and medical indemnity/liability insurance.

Bilateral sharing of experts is convenient when:

the requesting authority is aware of the resources available in the resource provider;



the agreement between the NAAs exists or is easy to establish;

the planning for the availability of the resources can easily be managed;

Whether the sharing of medical assessors is concluded directly between two NAAs or through a sharing platform, sustainability can only be ensured if all stakeholders are willing to consider global optimisation as a priority. The challenge is that the management system of each NAA may systematically reduce its resources so that all qualified medical assessors are fully occupied all the times. Such planning strategy does not provide any extra margin for contingencies and may easily drift towards understaffing. It is always difficult to swiftly adjust the number of permanently employed experts to the short term oversight needs. Therefore, while attempting to 'optimise' its own resources, each NAA may rely more and more on the experts from other NAAs and further reduce its staff. While this may work for a limited period of time, in the long run the sharing of experts may simply become impossible as all NAAs will be requesting qualified medical assessors while no NAA would be able to provide any. A similar reasoning applies when experts from the industry are shared.

The concept of sharing implies availability of resources. Availability means extra capacity. Therefore all stakeholders involved in the sharing are expected to coordinate their staffing strategies globally. This ensures global optimisation by reallocating resources so that no expert is underused and that the costs are shared based on the level of support obtained. Additionally, it is expected that activity planning is coordinated among all involved stakeholders.

AMC1 ARA.MED.125 Referral to the licensing authority

REFERRAL TO THE LICENSING AUTHORITY

- (a) The *aero-medical section of the* licensing authority should supply the AeMC or AME with all necessary information that led to the decision on aero-medical fitness.
- (b) The *aero-medical section of the* licensing authority should ensure that unusual or borderline and difficult cases or those not regulated in Part-MED or Part-ATCO.MED, as applicable, are evaluated on a common basis.
- (c) Each competent authority should define the time limit for the assessment of referred cases in their procedure regarding the management of referrals.

AMC 1 ARA.MED.128 Consultation Procedure

This procedure should include at least a summary of the consultation.

AMC1 ARA.MED.130 Medical certificate format

STANDARD EASA MEDICAL CERTIFICATE FORMAT

The format of the medical certificate should be as shown below.

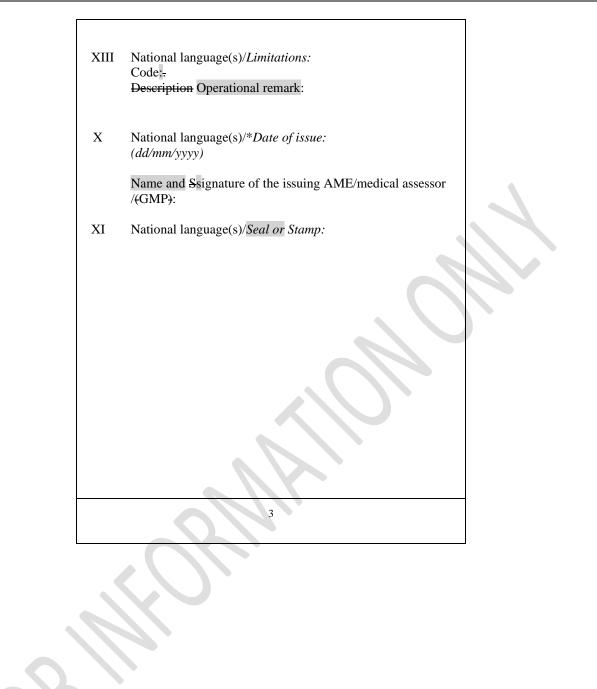
Competent authority name and logo (English and any language(s) determined by the competent authority)	Requirements
EUROPEAN UNION (English only)	"'European Union'" to be deleted for non- EU Member States Size of each page shall be one eighth A4



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Class 1/2/LAP		L CERTIFICATE	
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	III	National language(s)://Certificate number	
	IV	National language(s)+/	
		Last and first name of holder:	
	XIV	National language(s)://Date of birth: (dd/mm/yyyy):	
	VI	National language(s)/Nationality(ies):	
	VII	National language(s)/	
		Signature of holder:	
		2	

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ECG								
Audiogram (For class 1, and for class 2 w IR or en route IR)	ith							
Ophthalmological examination								
 (a) Licence holders shall n certificates, and student (1) are aware of any d safely exercise thos (2) take or use any prest the safe exercise of (3) receive any medica exercise of the priv (b) In addition, licence hold of their licence, seek as when they: (1) have undergone a s (2) have commenced th (3) have suffered any member of the flighted the safe and the	t pilots shall not fly ecrease in their me e privileges; scribed or non-presc the privileges of th l, surgical or other t ileges of the applica ders shall, without u ero-medical advice urgical operation or ne regular use of an significant persona	solo, at any time dical fitness that ribed medication e applicable licen reatment that is li able licence. fligh ndue delay and be from the AeMC, invasive procedu y medication; l injury involving	when they: might render t that is likely to ce; or kely to interfer t safety. efore exercising AME or GMP. rre; g incapacity to	hem unable to o interfere with re with the safe g the privileges as applicable.				

* Date of issue is the date the certificate is issued and signed



AMC1 ARA.MED.135(a) Aero-medical forms

APPLICATION FORM FOR A MEDICAL CERTIFICATE

The form referred to in ARA.MED.135(a) should reflect the information indicated in the following form and corresponding instructions for completion.

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LOGO

CIVIL AVIATION ADMINISTRATION/MEMBER STATE

APPLICATION FORM FOR A MEDICAL CERTIFICATE

Complete this page fully and in block capitals - Refer to instructions for completion.

MEDICAL IN CONFIDENCE

(1) State of licence issue:	(2) Media	edical certificate applied for: class 1 class 2 LAPI class 3 class 2 clas 2 class 2 class 2 class 2 cl					
(3) Surname:	(4) Previo	ous surname(s):	(12) Application: Initial Revalidation/Renewal				
(5) Forename(s):	(6) Date (of birth(dd/mm/yyyy):	(7) Sex: Male Female		(13) Reference/EAMR ID number:		
(8) Place and country of birth:	(9) Nation	nality:			(14) Type of licence applied for:		
(10) Permanent address:	(11) Post	al address (if different):					
Country: Telephone No.: Mobile No.: E-mail:	Country: Telephon	e No.:			(15) Occupation (principal): (16) Employer: (17) Last medical examination: Date: Place: Completed: No		
(18) Licence(s) held (type): Licence number: State of issue:		(19) Any limitations of Details:	on licence(s)/me	edical certificate held No 🗆 Yes 🗆		
(20) Have you ever had a medical certificate denied, suspended or revok licensing authority? No □ Yes □ Date: Country: Details:	ted by any	(21) Flight time total:			(22) Flight time since last medical:		
		(23) Aircraft class/typ	e(s) preser	ntly f	lown:		
(24) Any aviation accident or reported incident medical event whilst exe privileges of the licence since the last medical examination? No Yes Date: Place:	e (25) Type of flying intended Current/intended pilot activity: Commercial Non-commercial Other Single pilot Multi pilot						
Details:	(26) Present flying activity Current/intended ATC activity: ADI \square APS \square ACS \square ADV \square APP \square ACP \square						
 (27) Do you drink alcohol? □ No □ Yes, state average weekly amou Do you use drugs? □ No □ Yes, state the type: (29) Do you smoke tobacco? □ No, never □ No, date stopped: □ Yes, state type and amount: 	(28) Do you currently	use any m	edica				

General and medical history: Do you have, or have you ever had, any of the following? (Please tick a response for each question). If yes, give details in remarks section (30).

	Yes	No		Yes No		Yes 1	No	Family history of:	Yes	No
101 Eye trouble/eye operation			112 Nose, throat or speech disorder		123 Malaria or other tropical disease			170 Heart or vascular disease		
102 Spectacles and/or contact lenses ever	r		113 Head injury or concussion		124 A positive HIV test			171 High blood pressure		
worn			114 Frequent or severe headaches		125 Sexually transmitted disease			172 High cholesterol level		
103 Spectacle/contact lens prescriptions			115 Dizziness or fainting spells		126 Sleep disorder/apnoea syndrome			173 Epilepsy		
change since last medical exam.			116 Unconsciousness for any reason		127 Musculoskeletal illness/impairment			174 Mental illness or suicide		
104 Hay fever, other allergy			117 Neurological disorders; stroke,		128 Any other illness or injury			175 Diabetes		
105 Asthma, lung disease			epilepsy, seizure, paralysis, etc.		129 Admission to hospital			176 Tuberculosis		
106 Heart or vascular trouble			118 Psychological/psychiatric trouble of		130 Visit to medical practitioner or			177 Allergy/asthma/eczema		
107 High or low blood pressure			any sort	psychologist since last medical examination				178 Inherited disorders		
108 Kidney stone or blood in urine			119 Alcohol/drug/substance abuse misuse of psychoactive substances		131 Refusal of life insurance			179 Glaucoma		
109 Diabetes, hormone disorder			120 Attempted suicide or self-harm		132 Refusal of flying aviation licence					
					122 Madical sciencies from an fac			Females only:		
110 Stomach, liver or intestinal trouble			121 Motion sickness requiring medication		133 Medical rejection from or for military service	B Medical rejection from or for military service		150 Gynaecological, menstrual problems		
111 Deafness, ear disorder			122 Anaemia/sickle cell trait/other blood disorders		134 Award of pension or compensation for injury or illness			151 Are you pregnant?		

(30) Remarks: If previously reported and no change since, so state.

(31) Declaration: I hereby declare that I have carefully considered the statements made above and to the best of my belief they are complete and correct and that I have not withheld any relevant information or made any misleading statements. I understand that, if I have made any false or misleading statements in connection with this application, or fail to release the supporting medical information, the licensing authority may refuse to grant me a medical certificate or may withdraw any medical certificate granted, without prejudice to any other action applicable under national law.

CONSENT TO RELEASE OF MEDICAL INFORMATION: I hereby authorise the release of declare that I have been informed and I understand that all information provided to my AME contained in this report, and any or all its attachments to the AME and, where necessary and all information which is provided to my licensing authority and that relates to me, may be released to the medical assessor of the my licensing authority, other health professionals and medical administration staff as part of the aero-medical assessment process and to the medical assessor of the completion of a aero-medical assessment and-for oversight purpose will become and remain the property of the licensing authority, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.

NOTIFICATION OF DISCLOSURE OF PERSONAL DATA: I hereby declare that I have been informed and I understand that the data contained in my medical certificate according to ARA.MED.130, or ATCO.AR.F.005 if applicable, may be electronically stored and made available to my AME in order to provide historical data required in MED.A.035(b)(2)(ii)/(iii) or, if applicable, ATCO.MED.A.035(b)(2)(ii)/(iii), and to the medical assessors of the competent authorities of the Member States in order to facilitate the enforcement of ARA.MED.150 (c)(4).



Date	Signature of applicant	Signature of AME/(GMP)/(medical assessor)

INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FORM FOR A MEDICAL CERTIFICATE

This application form and all attached report forms will be transmitted to the licensing authority. Medical confidentiality shall be respected at all times.

The applicant should personally complete, in full, all questions (sections) on the application form. Writing should be legible and in block capitals, using a ball-point pen. Completion of this form by typing/printing is also acceptable. If more space is required to answer any questions, a plain sheet of paper should be used, bearing the applicant's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the application form for a medical certificate.

Failure to complete the application form in full, or to write legibly, may result in non-acceptance of the application form. The making of false or misleading statements or the withholding of relevant information in respect of this application may result in criminal prosecution, denial of this application and/or withdrawal of any medical certificate(s) granted.

17. LAST APPLICATION FOR A MEDICAL CERTIFICATE: State date (day, month, year) and place (town, country). Initial applicants state 'NONE'.
18. LICENCE(S) HELD (TYPE): State type of licence(s) held. Enter licence number and State of issue. If no licences are held, state 'NONE'.
19. ANY LIMITATIONS ON THE LICENCE(S)/MEDICAL CERTIFICATE: Tick appropriate box and give details of any limitations on your licence(s)/medical certificate, e.g. vision, colour vision, safety pilot, etc.
 20. MEDICAL CERTIFICATE DENIAL, SUSPENSION OR REVOCATION: Tick 'YES' box if you have ever had a medical certificate denied, suspended or revoked, even if only temporary. If 'YES', state date (dd/mm/yyyy) and country where it occurred.
21. FLIGHT TIME TOTAL: State total number of hours flown.
22. FLIGHT TIME SINCE LAST MEDICAL: State number of hours flown since your last medical examination.
23. AIRCRAFT CLASS/TYPE(S) PRESENTLY FLOWN: State name of principal aircraft flown, e.g. Boeing 737, Cessna 150, etc.
24. ANY AVIATION ACCIDENT OR REPORTED INCIDENT MEDICAL EVENT WHILST EXERCISING THE PRIVILEGES OF THE LICENCE SINCE THE LAST MEDICAL EXAMINATION: If 'YES' box ticked, state date (dd/mm/yyyy) and country of
accident/incident occurrence and provide details.
25. TYPE OF FLYING INTENDED CURRENT/INTENDED PILOT ACTIVITY: State whether airline, charter, single-pilot, commercial air transport, carrying passengers, agriculture, pleasure, etc.
Please-tick the appropriate box regarding the intended activity during the following certification period:
 Commercial, non-commercial or other (for other please specify the type of operation) Single-pilot or multi-pilot
26. PRESENT FLYING ACTIVITY CURRENT/INTENDED ATC ACTIVITY: Tick appropriate box to indicate whether you fly as the SOLE pilot or not. Please-tick the appropriate box regarding the intended activity during the following certification period e.g. ADI, APS, ACS
27. DO YOU DRINK ALCOHOL OR USE DRUGS? Tick applicable box. If yes, state weekly alcohol consumption e.g. 2 litres of beer.
28. DO YOU CURRENTLY USE ANY MEDICATION?: If 'YES', give full details - name, how much you take and when, etc. Include any non-prescription medication.
29. DO YOU SMOKE TOBACCO? Tick applicable box. Current smokers state type (cigarettes, cigars, pipe) and amount (e.g. 2 cigars daily; pipe – 1 oz. weekly)
30. GENERAL AND MEDICAL HISTORY All items under this heading from number 101 to 179 inclusive should have the answer 'YES' or 'NO' ticked. You should tick 'YES' if you have ever had the condition in your life and describe the condition and approximate date in the (30) remarks section. All questions asked are medically important even though this may not be readily apparent. Items numbered 170 to 179 relate to immediate family history, whereas items numbered 150 to 151 should be answered by female applicants only.



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Light Aircraft Pilot Licence [*] And whether Fixed Wing / Rotary Wing / Both Air Traffic Controller Other – Please specify *Please specify whether Fixed Wing / Rotary Wing / Both	If information has been reported on a previous application form for a medical certificate and there has been no change in your condition, you may state 'Previously reported; no change since'. However, you should still tick 'YES' to the condition. Do not report occasional common illnesses such as colds.
15. OCCUPATION (PRINCIPAL): Indicate your principal employment.	
16. EMPLOYER: If principal occupation is pilot, then state employer's name or if self-	
employed, state 'self'.	31. DECLARATION AND CONSENT TO OBTAINING AND RELEASING INFORMATION NOTIFICATION OF DISCLOSURE OF PERSONAL DATA:
	Do not sign or date these declarations until indicated to do so by the AME/GMP who will act as witness and sign accordingly.

AMC1 ARA.MED.135(b);(c) Aero-medical forms

MEDICAL EXAMINATION REPORT FORMS

The forms referred to in ARA.MED.135(b) and (c) should reflect the information indicated in the following forms and corresponding instructions for completion.



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I hereby certify that I/my AME group have personally examined the applicant named on this medical examination report and that this report with any attachment embodies my findings completely and correctly.							
(250) Place and date:	AME name and address:	AME certificate No.:					
AME signature:							
	E-mail:						
	Telephone No.:						
	Telefax No.:						



Shaded areas do not require completion

MEDICAL EXAMINATION REPORT FORM FOR LAPL APPLICANTS

MEDICAL IN CONFIDENCE

Special referral Systolic District Inregular Normal Abnormal 2009 Head, Race, neck, scalp (218) Abdomen, hernia, liver, spleen Normal Abnormal (200) Mouth, throat, teeth (219) Ansu, rectum Normal Abnormal (200) Spesi, sinses (219) Ansu, rectum Normal Abnormal (210) Nose, sinsues (220) Genito-uning xystem Image: Special system Image: Special syste	(201) Examina Initial			(202) Heigh (cm)	nt (203) (kg)	Weight	(204) Col eyes	our (205) Colour hair	(206) Blood press seated (mmHg)		7) Pulse - te (bpm)	Rhythm:
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(212) Eyes - only & adoptic fundi (223) Spine, obver musculoskeletal (213) Eyes - only motility; nystagmus (223) Spine, obver musculoskeletal (214) Eyes - ocular motility; nystagmus (225) Psychianic Mental health (215) Langs, chest, breasts. (225) Psychianic Mental health (216) Heart (225) Spin, identifying marks and lymphatics (217) Vascular system (227) General systemic (218) Notes: Describe every abnormal finding. Enter applicable item number before each comment. Tisnal acuity Spectacles (220) Intermediate vision Spectacles (230) Intermediate vision Uncorrected Spin tison Uncorrected (231) Mean vision Uncorrected (231) Mean vision Uncorrected Spin tison Uncorrected (231) Mean vision Uncorrected (231) Mean vision Uncorrected Spin tison Ves Right eye Corr. to Left eye Corr. to Left eye Corr. to Spin tison Uncorrected Spin tison Uncorrected Spin tison Uncorrected Spin tison C			motility									
(213) Eyes - pupils and pupits (multi (223) Spine, other musculoskeletal				1c				, ,				
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(215) Lungs, chest, breasts (225) Syx-hittire Mennal lealth (216) Heart (220) Skin, dientifying marks and lymphates (217) Vascular system (227) General systemic (218) Notes: Describe every abnormal finding. Enter applicable item number before each comment. 'stand acuity (220) Skin, dientifying marks and lymphates (220) Distant Vision at 5m / form (230) Pathonary function (230) Intermediate vision Spectacles (230) Mean Vision Uncorrected (230) Mean Vision Uncorrected (230) Mean Vision Uncorrected (231) Mear Vision Uncorrected (231) Near Vision Uncorrected (231) Near Vision Uncorrected (231) Near Vision Uncorrected (232) Spectacles (233) Contact Lenses Yes No Yes No Yes No (232) Spectacles (233) Contact Lenses Yes No Yes No No (233) Spectacles No (234) Addition (241) ORI (FNT) (242) OBphtalmology (241) ORI (ethal) (242) OBphtalmology												
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(249) AME/GMP declaration:

I hereby certify that I have personally examined the applicant named on this medical examination report and that this report with any attachment embodies my									
findings completely and correctly.									
(250) Place and date: AME/GMP name and address: AME certificate No./GMP									
		identification No.:							
AME/GMP signature:									
	E-mail:								
	Telephone No.:								
	Telefax No.:								



INSTRUCTIONS FOR COMPLETION OF THE MEDICAL EXAMINATION REPORT FORMS

The AME performing the examination should verify the identity of the applicant.

All questions (sections) on the medical examination report form should be completed in full. If an otorhinolaryngology examination report form is attached, then questions 209, 210, 211, and 234 may be omitted. If an ophthalmology examination report form is attached, then questions 212, 213, 214, 229, 230, 231, 232, and 233 may be omitted.

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing/printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the AME's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the medical examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly, may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an AME may result in criminal prosecution, denial of an application or withdrawal of any medical certificate(s) granted.

Shaded areas do not require completion for the medical examination report form for the LAPL.

201 EXAMINATION CATEGORY - Tick appropriate box.

Initial – Initial examination for either LAPL, class 1, or 2 or 3; also initial examination for upgrading from LAPL to class 2, or class 2 to 1 (notate insert 'upgrading' in box 248).

Renewal/Revalidation - Subsequent ROUTINE examinations.

Extended Renewal/Revalidation - Subsequent ROUTINE examinations, which include comprehensive ophthalmological and otorhinolaryngology examinations.

- 202 HEIGHT Measure height, without shoes, in centimetres to nearest cm.
- 203 WEIGHT Measure weight, in indoor clothes, in kilograms to nearest kg.
- 204 COLOUR EYE State colour of applicant's eyes from the following list: brown, blue, green, hazel, grey, multi.
- 205 COLOUR HAIR State colour of applicant's hair from the following list: brown, black, red, fair, bald.
- 206 BLOOD PRESSURE Blood pressure readings should be recorded as Phase 1 for Systolic pressure and Phase 5 for Diastolic pressure. The applicant should be seated and rested. Recordings in mm Hg.
- 207 PULSE (RESTING) The pulse rate should be recorded in beats per minute and the rhythm should be recorded as regular or irregular. Further comments if necessary may be written in section 228, 248 or separately.

208 to 227 inclusive constitute the general clinical examination, and each of the boxes should be marked (with a tick) as normal or abnormal.

208 HEAD, FACE, NECK, SCALP - To include appearance, range of neck and facial movements, symmetry, etc.

- 209 MOUTH, THROAT, TEETH To include appearance of buccal cavity, palate motility, tonsillar area, pharynx and also gums, teeth and tongue.
- 210 NOSE, SINUSES To include appearance and any evidence of nasal obstruction or sinus tenderness on palpation.
- 211 EARS, DRUMS, EARDRUM MOTILITY To include otoscopy of external ear, canal, tympanic membrane. Eardrum motility by valsalva manoeuvre or by pneumatic otoscopy.
- 212 EYES ORBIT AND ADNEXA; VISUAL FIELDS To include appearance, position and movement of eyes and their surrounding structures in general, including eyelids and conjunctiva. Visual fields check by campimetry, perimetry or confrontation.
- 213 EYES PUPILS AND OPTIC FUNDI To include appearance, size, reflexes, red reflex and fundoscopy. Special note of corneal scars.
- 214 EYES OCULAR MOTILITY, NYSTAGMUS To include range of movement of eyes in all directions; symmetry of movement of both eyes; ocular muscle balance; convergence; accommodation; signs of nystagmus.
- 215 LUNGS, CHEST, BREASTS To include inspection of chest for deformities, operation scars, abnormality of respiratory movement, auscultation of breath sounds. Physical examination of female applicant's breasts should only be performed with informed consent.
- 216 HEART To include apical heartbeat, position, auscultation for murmurs, carotid bruits, palpation for thrills.
- 217 VASCULAR SYSTEM To include examination for varicose veins, character and feel of pulse, peripheral pulses, evidence of peripheral circulatory disease.
- 218 ABDOMEN, HERNIA, LIVER, SPLEEN To include inspection of abdomen; palpation of internal organs; check for inquinal hernias in particular.
- 219 ANUS, RECTUM Examination only on clinical indication with following an informed consent.
- 220 GENITO-URINARY SYSTEM To include renal palpation; inspection palpation male/female reproductive organs only on clinical indication with following an informed consent.
- 221 ENDOCRINE SYSTEM To include inspection, palpation for evidence of hormonal abnormalities/imbalance; thyroid gland.
- 222 UPPER AND LOWER LIMBS, JOINTS To include full range of movements of joints and limbs, any deformities, weakness or loss. Evidence of arthritis.
- 223 SPINE, OTHER MUSCULOSKELETAL To include range of movements, abnormalities of joints.
- 224 NEUROLOGIC REFLEXES ETC. To include reflexes, sensation, power, vestibular system balance, romberg test, etc.
- 225 PSYCHIATRIC MENTAL HEALTH- To include appearance, appropriate mood/thought, unusual behaviour.
- 226 SKIN, IDENTIFYING MARKS AND LYMPHATICS To include inspection of skin; inspection, palpation for lymphadenopathy, etc. Briefly describe scars, tattoos, birthmarks, etc. which could be used for identification purposes.
- 227 GENERAL SYSTEMIC All other areas, systems and nutritional status.



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- 228 NOTES Any notes, comments or abnormalities to be described extra notes if required on separate sheet of paper, signed and dated.
- 229 DISTANT VISION AT 5/6 METRES Each eye to be examined separately and then both together. First without correction, then with spectacles (if used) and lastly with contact lenses, if used. Record visual acuity in appropriate boxes. Visual acuity to be tested at either 5 or 6 metres with the appropriate chart for the distance.
- 230 INTERMEDIATE VISION AT 100 CM Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses if used. Record visual acuity in appropriate boxes as ability to read N14 at 100 cm (Yes/No).
- 231 NEAR VISION AT 30-50 CM. Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses, if used. Record visual acuity in appropriate boxes as ability to read N5 at 30-50 cm (Yes/No).

Note: Bifocal contact lenses and contact lenses correcting for near vision only are not acceptable.

- 232 SPECTACLES Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or lookover.
- 233 CONTACT LENSES Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gaspermeable or disposable.
- 313 COLOUR PERCEPTION Tick appropriate box signifying if colour perception is normal or not. If abnormal; state number of plates of the first 15 of the pseudo-isochromatic plates (Ishihara 24 plates) have not been read correctly.
- HEARING Tick appropriate box to indicate hearing level ability as tested separately in each ear at 2 m.
- 235 URINALYSIS State whether result of urinalysis is normal or not by ticking appropriate box. If no abnormal constituents, state NIL in each appropriate box.
- 236 PULMONARY FUNCTION When required or on indication, state actual FEV₁/FVC value obtained in % and state if normal or not with reference to height, age, sex and race.
- 237 HAEMOGLOBIN Enter actual haemoglobin test result and state units used. Then state whether normal value or not, by ticking appropriate box.
- 238 to 244 inclusive: ACCOMPANYING REPORTS One box opposite each of these sections must be ticked. If the test is not required and has not been performed, then tick the NOT PERFORMED box. If the test has been performed (whether required or on indication) complete the normal or abnormal box as appropriate. In the case of question 244, the number of other accompanying reports must be stated.
- 247 AME RECOMMENDATION The applicant's name, date of birth and reference number, should be entered here in block capitals. The applicable class of medical certificate should be indicated by a tick in the appropriate box. If a fit assessment is recommended and a medical certificate has been issued, this should be indicated in the appropriate box. An applicant may be recommended as fit for a lower class of medical certificate (e.g. class 2), but also be deferred or recommended as unfit for a higher class of medical certificate (e.g. class 1). If an unfit recommendation is made, applicable Part-MED paragraph references should be entered. If an applicant is deferred for further evaluation, the reason and the doctor or licensing authority to whom the applicant is referred should be indicated.
- 248 COMMENTS, LIMITATIONS, ETC. The AME's findings and assessment of any abnormality in the history or examination, should be entered here. The AME should also state any limitation required.
- 249 AME DETAILS The AME should sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the relevant section with his/her designated AME stamp incorporating his/her AME number. The GMP identification no. is the number provided by the national medical system.
- 250 PLACE AND DATE The place (town or city) and the date of examination should be entered here. The date of examination is the date of the general examination and not the date of finalisation of the form. If the medical examination report is finalised on a different date, the date of finalisation should be entered in section 248 as 'Report finalised on'.

GM1 ARA.MED.135(b);(c) Aero-medical forms

OPHTHALMOLOGY AND OTORHINOLARYNGOLOGY EXAMINATION REPORT FORMS

The ophthalmology and otorhinolaryngology examination report forms may be used as indicated in the following forms and corresponding instructions for completion.

ency of the European Union

OPHTHALMOLOGY EXAMINATION REPORT FORM

Complete this page fully and in block capitals - Refer to instructions for completion.

MEDICAL IN CONFIDENCE

Applicant's details						1.			LIVEL	
(1) State applied to:			(2) Medica	al certificate appli		class 1 class 3		lass 2		
(3) Surname:			(4) Previou	us surname(s):		(12) Application: Initial Revalidation/Renewal				
(5) Forename(s):			(6) Date of birth: (7) Ma			Sex: e □		ence number		
(301) Consent to release of all information provided to r to the medical assessor of th these documents or electron and remain the property of Medical confidentiality will	ny AME, co he my licen ically store the licensir	ontained in this rep sing authority and d data are to be us ag authority, provi	ort and any o to the medi ed for comp	r all its attachment ical assessor of the letion of a medic	nts to th ne comp al asses	at I have be <u>e AME</u> and petent authors ssment and	l , where nec ority of my for oversig	essary , may l AME, recog ht purpose w	be relea nising ill becc	isec tha
Date	e of applicant	Signature of AME								
(302) Examination category Initial Revalidation Renewal Special referral	: (3 □ □ □	03) Ophthalmolog	cical history:					2		
linical examination		[]		Visual acuity						
Check each item		Normal A	bnormal	(314) Distan	t vision Uncori			Spectacles	S Cont lense	
(304) Eyes, external & eyeli	ds			Right eye			rrected to			_
(305) Eyes, Exterior				Left eye			rrected to			
(slit lamp, ophth.				Both eyes			rrected to			
306) Eye position and move	ements			(315) Interm	(315) Intermediate vision at 1			Spectacles		
307) Visual fields (confront	tation)			Dight ave	Uncorrected				lense	żS
	(ation)			Right eye Left eye			rrected to			
(308) Pupillary reflexes (309) Fundi (Ophthalmoscopy)				Both eyes	-		rrected to			
(310) Convergence	cm			(316) Near v		t 30-50cm	litered to	Spectacles		
(211) Assemmedation	D			Dight ava	Uncor		rrected to	1	lense	es
(311) Accommodation D				Right eye Left eye			rrected to		-	
(312) Ocular muscle balance	e (in prisme	dioptres)		Both eyes			rrected to			
Distant at 5m/6m		Near at 30-50 c	m	Dour eyes		0.01			,	
Ortho	Ortho			(317) Refraction		Sph	Cylinder	Axis	Near (add	
Eso	Eso			Right eye			I		(uuu	
Exo				Left eye					-	
Hyper	Нуре	er		Actual refrac	escription ba	sed				
Cyclo	Cycle	0					-	-		
Tropia Yes No	Phor			(318) Specta	cles		(319) (Contact lense	s	
Fusional reserve testing Nor	t performed	Normal Ab	normal	Yes D No D			Yes D No D			
(313) Colour perception		-		Type:			Type:			
Pseudo-Isochromatic plates		pe: Ishihara (24 pl	ates)							
No of plates: No of errors:				(320) Intra-0		pressure				
Advanced colour perception testing indicated Yes Method:			No	Right (mmH	g)		Left (mmHg)			
Colour SAFE Colour UNSAFE				Method			Normal 🗆 Abnormal 🗆			
21) Ophthalmological re	marks and	l recommendation	ən:							
	•									
22) Examiner's declaration I hereby certify that I/my a named oin this medical e	AME group									
correctly.			I	,			•	U ' F'	5	
(323) Place and date: Ophth examiner			iner's n Nan	ne and address: (block	AME or	or eye specialist stamp with No.:			
capitals)										
AME or eye specialist sign	nature:									
		E								
		E-mail: Telephone N	No.:							
		Telefax No.								



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INSTRUCTIONS FOR COMPLETION OF THE OPHTHALMOLOGY EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or ophthalmology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the ophthalmology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or ophthalmology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 301) with the examiner countersigning as witness.

302 EXAMINATION CATEGORY – Tick appropriate box.

Initial - Initial examination for either class 1 or 2; also initial examination for upgrading from class 2 to 1 (notate insert 'upgrading' in section 303).

Renewal/Revalidation - Subsequent comprehensive ophthalmological examinations (due to refractive error).

Special referral - NON-ROUTINE examination for assessment of an ophthalmological symptom or finding.

- 303 OPHTHALMOLOGICAL HISTORY Detail here any history of note or reasons for special referral.
- 304 to 309 inclusive: CLINICAL EXAMINATION These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- 310 CONVERGENCE Enter near point of convergence in cm, as measured using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- 311 ACCOMMODATION Enter measurement recorded in dioptres using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- 312 OCULAR MUSCLE BALANCE Ocular muscle balance is tested at distant 5 or 6 m and near at 30-50 cm and results recorded. Presence of tropia or phoria must be entered accordingly and also whether fusional reserve testing was NOT performed and if performed whether normal or not.
- 313 COLOUR PERCEPTION Enter type of pseudo-isochromatic plates (ishihara) as well as number of plates presented with number of errors made by examinee. 15 plates should normally be presented from the 24 plate series, in random order. State whether advanced colour perception testing is indicated and what methods used (which colour lantern or anomaloscopy) and finally whether judged to be colour safe or unsafe. Advanced colour perception testing is usually only required for initial assessment, unless indicated by change in applicant's colour perception.
- 314–316 VISUAL ACUITY TESTING AT 5 m/6 m, 1 m and 30-50 cm Record actual visual acuity obtained in appropriate boxes. If correction not worn nor required, put line through corrected vision boxes. Distant visual acuity to be tested at either 5 m or 6 m with the appropriate chart for that distance.
- 317 REFRACTION Record results of refraction. Indicate also whether for class 2 applicants, refraction details are based upon spectacle prescription.
- 318 SPECTACLES Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or lookover.
- 319 CONTACT LENSES Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gaspermeable, disposable.
- 320 INTRA-OCULAR PRESSURE Enter intra-ocular pressure recorded for right and left eyes and indicate whether normal or not. Also indicate method used applanation, air etc.
- 321 OPHTHALMOLOGICAL REMARKS AND RECOMMENDATION Enter here all remarks, abnormal findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations, the examiner may contact the AMS medical assessor of the licensing authority for advice before finalising the report form.
- 322 OPHTHALMOLOGY EXAMINER'S DETAILS The ophthalmology examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.
- 323 PLACE AND DATE Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ophthalmology examination report is finalised on a different date, enter date of finalisation on section 321 as 'Report finalised on'.



OTORHINOLARYNGOLOGY (ENT) EXAMINATION REPORT FORM

Complete this page fully and in block capitals – Refer to instructions for completion.

Applicant's details			-				MEDICAI	L IN CON	IFIDENCI	E	
(1) State applied to:			(2) Medical certificate applied for:				class 1 class 3		class 2		
(3) Surname:			(4) Previous surname(s):				(12) Application: Initial				
(5) Forename(s):					(7) S Mal Fem	e 🗆					
(401) Consent to release of medical in all information provided to my AME, co to the medical assessor of the my licens these documents or electronically stored and remain the property of the licensin Medical confidentiality will be respected	ntained in this sing authority l data are to b g authority , p	and to the used for c	any or all its at medical asses completion of	tachment sor of the a medical	are th s to th comp asses	at I have b e AME and betent auth sment and	d, where new ority of my for oversig	xessary , m AME, re ht purpos	nay be rele cognising e will bec	ased that ome	
Date Signature			e of applicant Signal				ture of AME				
(402) Examination category: (44 Initial Special referral	03) Otorhinola	aryngologic	al (ENT) histo	ory:				2			
Clinical examination			41 1	(110)	P						
Check each item (404) Head, face, neck, scalp		formal	Abnormal	(419)	Pure	tone audi dB	ometry HL (hearing	level)			
(405) Buccal cavity, teeth				Hz		Right ear		Left ea	ır		
(406) Pharynx					50 00						
(407) Nasal passages and naso-pharyn nx (incl. anterior rhinoscopy)	6				00						
(408) Vestibular system incl. Romberg t	est				00						
(409) Speech					00						
(410) Sinuses (411) Ext acoustic meati, tympanic mem	branes	_			00						
(412) Pneumatic otoscopy	ioranes				00						
(413) Impedance tTympanometry includ Valsalva meanoeuvre (initialonly clinically indicated)				(420)	Audi	ogram					
						o = F x = L	0	=			
Additional testing (if indicated)		Normal	Abnormal	dB/H							
(414) Speech audiometry discrimination test with/without	performed			1	0						
hearing aids,as applicable (415) Posterior rhinoscopy				1	0						
(416) EONG; spontaneous and					0						
positional nystagm n us					0						
(417) Differential c Caloric test or vestibular auto rotation test					0				+		
(418) Mirror or fibre laryngoscopy					0						
					0						
(421) Otorhinolaryngology remarksand recommendation:					0			\vdash	+		
(421) Otor minorar yngology remarks anu recommendation .				10							
				11							
				Hz	0 250	500 100	0 2000 3	000 4000) 6000 80	000	
(422) Examiner's declaration: I hereby certify that I/ my AME group I										cant	
named oin this medical examination report and that this report with any attach (423) Place and date: ORL examiner's nName and capitals)							or ENT spe			o:	
AME or ENT specialist signature:	E-mail: Telephon Telefax N										



INSTRUCTIONS FOR COMPLETION OF THE OTORHINOLARYNGOLOGY (ENT) EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or otorhinolaryngology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the otorhinolaryngology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or otorhinolaryngology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 401) with the examiner countersigning as witness.

402 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for class 1; also initial examination for upgrading from class 2 to 1 (notate insert 'upgrading' in section 403)

Special Referral – NON-ROUTINE examination for assessment of an ORL (ENT) symptom or finding

403 OTORHINOLARYNGOLOGICAL (ENT) HISTORY – Detail here any history of note or reasons for special referral.

- 404-413 inclusive: CLINICAL EXAMINATION These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 421.
- 414-418 inclusive: ADDITIONAL TESTING These tests are only required to be performed if indicated by history or clinical findings and are not routinely required. For each test one of the boxes must be completed if the test is not performed then tick that box if the test has been performed then tick the appropriate box for a normal or abnormal result. All remarks and abnormal findings should be entered in section 421.
- 419 PURE TONE AUDIOMETRY Complete figures for dB HL (hearing level) in each ear at all listed frequencies.
- 420 AUDIOGRAM Complete audiogram from figures as listed in section 419.
- 421 OTORHINOLARYNGOLOGY (ENT) REMARKS AND RECOMMENDATION Enter here all remarks, abnormal findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations the examiner may contact the AMS medical assessor of the licensing authority for advice before finalising the report form.
- 422 OTORHINOLARYNGOLOGY (ENT) EXAMINER'S DETAILS The otorhinolaryngology (ENT) examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.
- 423 PLACE AND DATE Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ORL (ENT) examination report is finalised on a different date, enter date of finalisation in section 421 as 'Report finalised on'.



AMC2 ARA.MED.150 Record-keeping

Reporting health data of pilots above the age of 60

For pilots above the age of 60 the competent authorities performing the analysis of health data should report in an aggregated manner at least the following data:

- (a) number and proportion of pilots above the age of 60 assessed as unfit, as well as the most common medical conditions that triggered unfitness and the age distribution
- (b) proportion of incapacitation (partial and total) events among this category of pilots and the most common medical and, if applicable, the operational conditions that triggered incapacitation
- (c) the proportion of pilots above the age of 60 who did not revalidate their medical certificate
- (d) any safety concerns based on the trends identified as a result of the data analysis.

AMC1 ARA.MED.151 Medical Confidentiality

To ensure medical confidentiality, all medical reports and records should be securely held with accessibility restricted to personnel authorised by the medical assessor.





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SECTION II — AERO-MEDICAL EXAMINERS (AMEs)

AMC1 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

INSPECTION OF THE AME PRACTICE

Before issuing the Upon request for issuing, revalidation, renewal or change of an AME certificate, the competent authority should conduct an inspection of the AME practice to verify compliance with ARA.MED.200(a).

For applicants for an AME Certificate to exercise the privileges of class 2 medical certification only, a virtual inspection of the AME premises may be acceptable. In case of concerns regarding compliance with this regulation, an on-site inspection should be conducted.

AMC2 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

The procedure should include:

- (a) for the initial issue or extension of privileges, evidence of successful completion of an approved aviation medicine training course in accordance with the privileges of the AME certificate applied for;
- (b) for revalidation and renewal, evidence of refresher training and maintenance of aero-medical competency

AMC1 ARA.MED.246 Cooperative oversight of AMEs and AeMCs

The cooperative oversight procedure may include oversight tasks to be undertaken by the competent authority of the Member State where the AME/AeMC has its secondary place of business.

The results of the oversight should be shared among the Member States involved.

AMC1 ARA.MED.250(a) Limitation, suspension or revocation of an AME certificate

(a) The competent authority should consider as part of the assessment of compliance, the compliance with the national procedures in place to implement the applicable requirements. (b) The competent authority should consider as part of the criteria for continuing certification the level of aero-medical competence

SECTION III — MEDICAL CERTIFICATION

AMC1 ARA.MED.315(a) Review of examination reports

GENERAL

- (a) The process to review examination and assessment reports received from AeMCs, AMEs and GMPs should aim to check all reports received.
- (b) The aero-medical section of the licensing authority should develop a performance assessment process for AMEs to should take account of the proportion of inconsistencies or errors foundin the assessment process and, adapt the sample size accordingly and consider corrective actionto review all reports if necessary.



(c) The aero-medical section of the licensing authority should implement a medical review process of all examination and assessment reports received from AeMCs, AMEs and GMPs certified by the competent authority of another Member State.

AMC1 ARA.MED.325 Secondary review procedure

- (a) The secondary review procedure should specify:
 - (1) the establishment of a review board and its composition;
 - (2) how the accredited medical conclusions of the review board will be implemented.
- (b) The composition of the review board should be decided by the aero-medical section of the licensing authority. It may be preceded by the advice of the medical assessor and may consist of, but no limited to:
 - (1) clinical medical experts according to the case;
 - (2) other technical experts according to the case;
 - (3) aviation medicine experts;
 - (4) AME with privileges according to the class on medical certificate in question.

AMC1 ARA.MED.330 Special medical circumstances

GENERAL

The protocol should:

- (a) assess the incapacitation risk
- (b) assess the risk of subtle impairment of performance;
- (c) undertake a risk-benefit analysis;
- (d) include a review of the regulations in use in other major aviation states and ICAO;
- (e) determine which class of medical certificate is included in the scope;
- (f) estimate the number of pilots likely to be included;
- (g) list all anticipated risks to the protocol and provide a risk management strategy including appropriate limitations for every anticipated risk. Where the risk of subtle impairment of performance is identified, the protocol should include requirements for minimum simulator testing or minimum line-flying under supervision or both.
- (h) nominate medical research experts, if necessary, to provide advice on research methods.

AMC1 ARA.MED.330(b)(c) Special medical circumstances

GENERAL

Initial medical certificates issued on the basis of a research protocol should only be issued by the competent authority. Thereafter, the competent authority should decide whether the AeMC or AME may issue the medical certificate.

GM1 ARA.MED.330 Special medical circumstances

GENERAL



- (a) When the terms 'medical assessment protocol', 'research protocol' and 'protocol' (as mentioned in ARA.MED.330 and its associated AMC) are used, they all refer to a 'medical assessment protocol'.
- (b) The protocol is to enable experience to be gained on special medical circumstances in a controlled manner. This is to facilitate a better understanding of the treatment or condition, so that an evidence-based decision concerning its implementation may be considered.
- (c) The protocol and its implementation should comply with the principles described in the following publication by the World Medical Association (WMA): 'WMA Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects', as last amended.

1.1.2. AMC/GM to Part ORA

Subpart AeMC SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CENTRES (AeMCs) is amended as follows:

Subpart AeMC – Aero-medical Centres

SECTION I — GENERAL

GM1 ORA.AeMC.105 Scope

The AeMC should support the regional AME peer groups in order to enhance the professional expertise

AMC1 ORA.AeMC.115 Application

GENERAL

- (a) The documentation for the approval of an AeMC should include the names and qualifications of all medical staff, a list of medical and technical facilities for initial class 1 and class 3 aero-medical examinations, as applicable according to the scope of the AeMC approval and of supporting specialist consultants.
- (b) The AeMC should provide details of clinical attachments to hospitals, medical institutions and/or specialists.
- (b) Medical staff should cover the standard required medical examinations to be performed within the organisation of the AeMC
- (c) Contracted activities with designated hospitals or medical institutes for the purpose of additional specialist medical examinations include clinical attachments or liaison with hospitals, medical institutions and/or specialists.

AMC1 ORA.AeMC.135 Continued validity

EXPERIENCE

(a) A total of Atat least 200 class 1, class 3 or equivalent aero-medical examinations and assessments should be performed at the AeMC every year.



- (b) In Member States where the number of aero-medical examinations and assessments mentioned in (a) cannot be reached due to a low number of professional pilots or ATCOs, a proportionate number of class 1 or class 3 aero-medical examinations and assessments should be performed.
- (c) In these cases, the continuing experience of the head of AMEs in the AeMC and aero-medical examiners on staff should may also be ensured by them performing aero-medical examinations and assessments for:
 - (1) class 2 medical certificates as established in Part-MED; and/or
 - (2) third country class 1, class 3 or equivalent medical certificates.
- (d) Aero-medical research including publication in peer reviewed journals may also be accepted as contributing to the continued experience of the head of, and aero-medical examiners at, an AeMC.

SECTION II — MANAGEMENT

AMC1 ORA.AeMC.200 Management system

- (a) Assessment of the AeMC's management system by a national medical authority may be included as a part of the AeMC overall management system;
- (b) In order to maintain personnel trained and competent to perform their tasks as specified in ORA.GEN.200(a)(4) the management system should ensure that each AME performs a sufficient number of aero-medical assessments to meet the professional standards of an AeMC. The required activity of each AME should be specified in the management system.

GM2 ORA.AeMC.200 Management system

The management system should encompass regular exchange of professional expertise including case analysis.

AMC1 ORA.AeMC.205(a) Contracted activities

The standard required medical examinations should at least encompass the following specialities: ophthalmology including colour vision, otorhinolaryngology, cardiology and mental health

AMC1 ORA.AeMC.210 Personnel requirements

GENERAL

- (a) The aero-medical examiner (AME) should have held AME class 1 privileges, as applicable in accordance with the scope defined in the terms of approval attached to the AeMC's certificate for at least 5 years and have performed at least 200 aero-medical examinations and assessments for a class 1, class 3 or equivalent medical certificate before being nominated as head of an AeMC.
- (b) The AeMC may provide practical AME training for persons fully qualified and licensed in medicine.

AMC1 ORA.AeMC.215 Facility requirements

MEDICAL-TECHNICAL FACILITIES



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(a) Cardiology

Facilities to perform:

- (1) 12-lead resting ECG;
- (2) stress ECG;
- (3) 24-hour blood pressure monitoring; and
- (4) 24-hour heart rhythm monitoring.
- (b) Ophthalmology

Facilities for the examination of:

- (1) near, intermediate and distant vision;
- (2) external eye, anatomy, media and fundoscopy;
- (3) ocular motility;
- (4) binocular vision;
- (5) colour vision (anomaloscopy or equivalent);
- (6) visual fields;
- (7) refraction; and
- (8) heterophoria.
- (c) Hearing
 - (1) pure-tone audiometer
- (d) Otorhinolaryngology (ENT)

Facilities for the clinical examination of mouth and throat and:

- (1) otoscopy;
- (2) rhinoscopy;
- (3) tympanometry or equivalent; and
- (4) clinical assessment of vestibular system.
- (e) Examination of pulmonary function
 - (1) spirometry
- (f) The following facilities should be available at the AeMC or arranged with a service provider:
 - (1) clinical laboratory facilities; and
 - (2) ultrasound of the abdomen;
 - (3) exercise ECG;
 - (4) 24-hour heart rhythm monitoring;
 - (5) 24-hour blood pressure monitoring; and



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(6) mental health assessment including psychometric testing.



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1.1.3. AMC/GM to Part MED

Subpart B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES is amended as follows:

SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

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

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 2 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 factors 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 factors assessment should take place at least once every 5 years for applicant 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

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- (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

[...]

AMC2 MED.B.010 Cardiovascular system

[...]

- (b) General
 - (1) Cardiovascular risk factor assessment

Cardiovascular risk factors assessment should take place at least once every 5 years for applicant 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 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.

[...]

- (I) Rhythm and conduction disturbances
- [...]
- (6) Complete right bundle branch block

Applicants with complete right bundle branch block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

[...]

GM1 MED.B.010(b) Cardiovascular system

(1) 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 years 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 with your most common target population. No risk calculator is perfect and in the decision to which tools should



be used an assessment of advantages and disadvantages should be made. 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".

(2) Cardiovascular assessment

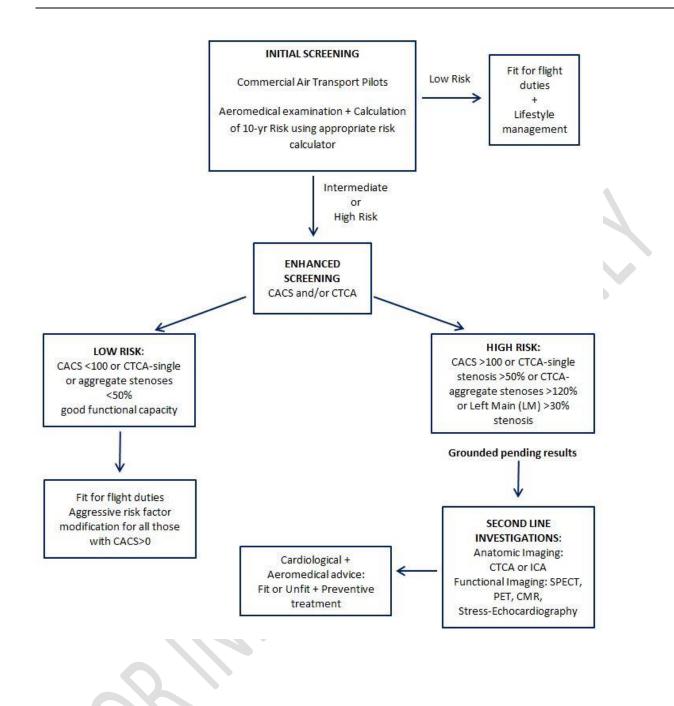
It is recommended that for applicants involved in single pilot HEMS operations who have reached the age of 60, the cardiovascular assessment considers the risk level when deciding on enhanced screening investigations.

In this regard the following flow chart algorithm adapted by Simons et al. (2019) from Gray et al.(2019)

This algorithm 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]





AMC1 MED.B.015 Respiratory system

- (a) Examination
 - (1) Spirometry

A spirometric examination is required by MED.B.015(b) & (c) for initial examination and on clinical indication class 1 applicant 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





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(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, a history of cardiovascular, cerebro-vascular, metabolic and ENT pathology.

GM1 MED.B.015 Respiratory system

Screening obstructive sleep apnoea (OSA) syndrome

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.

AME-Guidance :

Indicators to initiate OSA-Evaluation

- History interview including at least the following:
- o 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:
 - o BMI >30
 - Previous bariatric history
 - Neck circumference: <40 cm or >40
 - Diagnosed arterial hypertension
 - Heart troubles
 - Arrhythmia
 - Congestive heart failure
 - CHD
 - o Previous TIA, stroke
 - Diabetes Type 2
 - o 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)



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 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.

[...]

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 a dynamic visual acuity tests using different levels of luminance could be considered;
- (3) examination of the external eye, anatomy, media (slit lamp) and fundoscopy;
- (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 fundoscopy; and
- (4) contrast sensitivity assessment test for applicants above the age of 60; and
- (5) further examination on clinical indication.

[...]

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;
 - visual acuities near, intermediate and distant vision (uncorrected and with best optical correction if needed);
 - (iii) examination of the external eye, anatomy, media and fundoscopy;
 - (iv) ocular motility;
 - (v) binocular vision;
 - (vi) visual fields;
 - (vii) colour vision;

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- (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 fundoscopy;
- (4) contrast sensitivity assessment test for applicants above the age of 60; and
- (5) further examination on clinical indication.
- [...]



1.1.4. AMC/GM to Part SPA

Regulation 965 – Annex V (Part SPA)

Subpart J – HELICOPTER EMERGENCY MEDICAL SERVICE OPERATIONS is amended as follows:

SUBPART J – HELICOPTER EMERGENCY MEDICAL SERVICE OPERATIONS

AMC1 SPA.HEMS.130(g)(1) Crew requirements

Operators should identify, as part of their safety risk assessment process, additional risks for flight crew members who have attained the age of 60 years and perform single pilot HEMS operations in accordance with FCL.065(a), including the negative effects of fatigue as a cardiovascular and cerebrovascular risk factor and take appropriate action to effectively mitigate those risks.

GM1 SPA.HEMS.130(g)(1) Crew requirements

Best practices for flight crew members above the age of 60 performing single pilot HEMS operations

Several studies have found that in general working population frequent exposure to long working hours (≥55 hours per week), frequent overtime work (3-4 hours overtime) or shift work is associated with increased risks of cardiovascular disease (including of fatal and non-fatal coronary heart disease (CHD) and atrial fibrillation) and cerebrovascular disease such as stroke.

In the context of the association of long work hours, overtime work, and shift work with an increased CVD risk, some authors recommend for general population countermeasures such as a limit of operation time to 40 hrs/week and working time up to 10 hours within 24 hours (Virtanen et al., 2018). Although such operational limitations might be considered to apply for pilots from the age of 60 onwards, it is not clear, due to lack of dedicated studies, how that will affect the cumulative CVD risk after numerous years of exposure to long and irregular working hours before their 60th birthday. However, by limiting the working hours the risk for CVD and cerebrovascular disease will not be further increased due to fatigue and, with time passing, this risk is expected to gradually reduce. A working hour limitation could also lead to a reduction in fatigue and an increase in the recovery of older pilots.

With regards to the above-mentioned considerations, it should be emphasized that sufficient sleep of good quality is the key factor in preventing fatigue and maintaining optimal performance and good health. Ideally, a pilot should have a continuous 8-hour sleep opportunity per 24 hours. Sleep should be facilitated in a dark and quiet environment allowing horizontal rest. Where the ideal 8 hours continuous rest is not possible due to operational constrains, the operator could consider additional mitigating measures within their FRMS/SMS. The operators should also give proper consideration to the period of the day when this rest period is scheduled in relation to the circadian rhythm of the flight crew members.

Operators could consider implementing a Fatigue Risk Management system (FRMS) tailored for the specific operational demands of the company. Pilots and managers should be educated to stimulate awareness of the safety implications of fatigue, recognise the signs of fatigue, and how to prevent fatigue by sufficient sleep and strategic naps.

Basic principles to consider for HEMS operators:

- (a) Form a Fatigue Safety Action Group including manager/head flight-OPS, planner, pilot(s)
- (b) Identify potential fatigue hazards, including accumulation of fatigue



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- (c) Assess fatiguing rosters (e.g. this can simply be done using Karolinska Sleepiness Scale or Samn-Perelli Fatigue Scale + assessment of sleep duration and quality using simple scale)
- (d) Estimate risk associated with identifiable hazard
- (e) Redesign rosters/rotations in conjunction with stakeholders
- (f) Monitor reduction of risk (e.g. using Karolinska Sleepiness Scale or Samn-Perelli Fatigue Scale + assessment of sleep duration and quality using simple scale)
- (g) Provide procedures and training (If necessary this might be done by external expert + online)
- (h) Make use of the continuous improvement plan-do-check-act principle of the SMS

AMC1 SPA.HEMS.130(g)(2) Crew requirements

Recurrent training and checking of pilots above the age of 60 performing single pilot HEMS operations:

- (a)Personnel providing training and checking for this category of pilots should aim, to the best of their abilities, to identify and document any signs of cognitive decline and to discuss their concerns with the pilot in question encouraging them to self-report the problems to the AME/AeMC, or Peer Support Programme. To detect possible neurocognitive shortcomings, essential cognitive factors contributing to flight performance should be incorporated in the regular mandatory License Proficiency Checks (LPC) or Operator Proficiency Checks (OPC). Attention should be focused on abilities to function under highly stressful demands, such as cockpit tasks under high time pressure.
- (b) Where signs of cognitive decline have been identified the report highlighting these signs should be shared without undue delay with the medical assessor of the licensing authority, as defined in Part-MED, for further assessment.
- (c) Where the training or checking report is inconclusive on whether or not the pilot has any kind of cognitive decline, the personnel providing the respective training or checking should consult with a class 1 aeromedical examiner (AME) or AeMC before allowing the pilot to resume their flying duties.
- (d) Transmission of any suspicion towards the medical assessor of the licensing authority or the AME/AeMC as defined in points 2 and 3 above should comply with the principles of medical confidentiality.

GM1 SPA.HEMS.130(g)(2) Crew requirements

(a) Information for examiners about operational signs of cognitive performance deficits.

Cognition encompasses many aspects of intellectual functions and processes such as: perception, attention, thought, the formation of knowledge, memory and working memory, judgment and evaluation, reasoning and computation, problem solving and decision making, comprehension and production of language. Cognitive processes use existing knowledge and discover new knowledge.

Cognitive decline is considered to begin from 40 years of age. There is large variation in the extent and functional effects of age-related impairment between people of the same age. The most important changes in cognition with normal aging are declines in performance on cognitive tasks that require one to quickly process or transform information to make a decision, including measures of speed of processing, working memory, and executive cognitive function.

(b) Cognitive functions and aviation

The cognitive functions generally assumed to impair with increasing age and considered important for a proper performance of all flying tasks are:

- (1) problem-solving and decision-making (e.g. diagnosis of faults and defects and taking action)
- (2) information processing within a required time frame (e.g. process information of flight, navigation and engine instruments, primary flight displays, radar, TCAS, radio voice communications, data-link, direct vision, crewmember communication, vibrations, noises and smells). With tasks involving both



speed and accuracy, older people tend to attach greater importance to accuracy, thereby slowing their speed of response.

- (3) perception (e.g. instrument monitoring)
- (4) memory (e.g. recall information given by air traffic control)
- (5) psychomotor coordination (e.g. flight control).

Signs of cognitive impairment can relate to any or all of the five functions listed above. It is generally accepted that experience can counter cognitive decline in active pilots up to a certain level.

To detect signs of neurocognitive performance deficits, above mentioned cognitive factors of flight performance should be assessed during the regular Operator Proficiency Checks (OPC) giving proper consideration to the List of competency elements and performance criteria described in GM1 to Appendix 5 to Annex I (Part-FCL) of Regulation (EU) 1178/2011 points (g) to (o) with particular focus on the following points:

- attitudes and behaviours appropriate to the safe conduct of flight, including recognising and managing potential threats and errors
- management of abnormal and emergency situations
- communication with ATC, ground personnel and crew, and HEMS crew

Particular attention on abilities to function under highly stressful demands, such as high time pressure is expected to allow the instructor or examiner to raise suspicions of deficits and referr the respective case to the medical assessor of the licensing authority or an AME.

GM2 SPA.HEMS.130(g)(2) Crew requirements

(a) Considerations concerning confidentiality in case an examiner would like to report possible signs of cognitive performance deficits of a candidate to the AME/AeMC

It is worth noting that the EASA legislation allows for the differences in data protection laws between member states. National data protection laws should be obeyed in all cases involving transfer of personal data to authorities, medical, and psychological personnel.

The personal data of flight crew who are candidates of recurrent checking tests should be handled in strict confidentiality. Personal data can only be shared with authorities, AMEs, and other relevant experts with the consensus of the candidate involved. For that, the information that will be reported has to be clearly described in a consensus agreement that is to be signed by the candidate.

Medical confidentiality is protected under EU Regulation 1178/2011. Confidentiality is an important ethical and legal duty but it is not absolute: legal (medical) requirements 1 state that confidentiality can be disclosed to the Appropriate Authority in case of "Imminent and high risk of harm to others" and "Failure to disclose would cause harm." In an aviation environment the "imminent and high risk of harm to others" can be translated into evidence that failure to disclose would create an imminent and severe threat to flight safety. It can be concluded that breaching of confidentiality is justified if the examiner determines that flight safety is threatened if the candidate would continue to fly, and the candidate refuses to sign the consensus document or refuses to self-report to operational and medical authority.

(b) Additional considerations and examples

It is anticipated that in the context of recurrent checking tests examiners may not come in a position where they have to breach confidentiality related to observed signs of neurocognitive performance deficits. If neurocognitive performance deficits would cause failure or partial failure of the test, the candidate will be reported to the authority and will not be allowed to exercise the privileges of her/his rating/license pending the results of a new test. Because the candidate is grounded flight safety will not be imminently endangered and therefore it is not necessary or allowable for the examiner to breach confidentiality. In such case the examiner shall provide evidence based on identifiable factual items explaining why the candidate's performance did not meet the required standards. If one or more of the problems might relate to performance-based signs of neurocognitive impairment (see document on Signs



of Cognitive performance deficits), the examiner or the authority should report this to an AME/AeMC with a written and signed consensus of the candidate. In case there are signs of a cognitive performance deficit, the AME/authority can demand a neurophysiological assessment before a re-examination check is to be performed. If a candidate refuses to sign the consensus document, breaching of confidentiality is not justified because there is no imminent threat to flight safety because the candidate is grounded. In the case a candidate has successfully passed the check, s/he has shown that her/his performance is sufficient to exercise the privileges of the rating/license. There is no evidence for a threat to flight safety and thus no need to breach confidentiality.

If a result of a check is sufficient only by the narrowest margin and the examiner has found a possible sign of cognitive performance deficit, the examiner should describe her/his concerns in operational terms such as "diagnosing and decision making on engine failures took longer time than commonly needed" (which relates to the cognitive function of problem-solving and decision-making). The examiner should explain her/his concerns to the candidate and seek consensus of the candidate to share the concerns with the AME in order to discuss monitoring of possible cognitive decline by shortening the interval between the last and the next check and/or a neurophysiological assessment. If there is no consensus, breaching of confidentiality will not be justified because there is no imminent threat to flight safety because the candidate has passed the check. In that case the examiner could consider paying special attention to signs of cognitive performance deficit(s) during a next check.